Supreme Court, U.S.
FILED

No. 09-734

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OFFICE OF THE CLERK

In The

# Supreme Court of the United States

GEOFFREY S. AMES, M.D.,

*Petitioner,*

vs.

WASHINGTON STATE HEALTH DEPARTMENT
MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

*Respondent.*

**On Petition For Writ Of Certiorari To The Supreme Court Of The State Of Washington**

## APPENDIX, PART TWO
## PETITION FOR A WRIT OF CERTIORARI

WILLIAM R. BISHIN
*Counsel of Record*
WILLIAM R. BISHIN P.S.
1404 East Lynn
Seattle, WA 98112
(206) 323-7175

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

| | |
|---|---|
| In the Matter of the License to Practice as a Physician and Surgeon of:<br>GEOFFREY S. AMES, M.D., License No. MD 00026961,<br>Respondent. | Docket No. 02-06-A-1012MD |

TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

APPEARANCES

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Suite 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

Reported By
Duane W. Lodell
CCR #
LODELDW533N9

ROBERT H. LEWIS
& ASSOCIATES
Certified Court Reporters
5113 Pacific Highway East,
Suite 1
Fife, Washington 98424-2639
253.952.2030 – 1.877.952.2030
*Fax: 253.927.2520*

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* * * *

[2386] Ms. Paxton. They are hearing this case. I'm presiding over the hearing. There is a court reporter recording this proceeding. Mr. Keith Armstrong is the assistant attorney general, and he's representing the Department of Health. Mr. William Bishin, Attorney at Law, is here, representing Dr. Ames, who is present.

You've been designated to testify as a witness, I will ask the court reporter to swear you in at this time.

NEIL OGDEN,

having been first duly sworn by the Notary, testified as follows:

JUDGE DeBUSSCHERE: One requirement that I ask of you, Mr. Ogden – this is Health Law Judge Art DeBusschere – is that you are testifying as a fact witness. And I'd ask that – Of course, I understand you are employed with the FDA. And if you have documents there when you testify, if you are referring a document, we'd ask that you identify that document prior to your testimony, okay?

THE WITNESS: Yes.

JUDGE DeBUSSCHERE: Do you understand that requirement?

THE WITNESS: I do.

JUDGE DeBUSSCHERE: Can you hear me okay?

[2387] THE WITNESS: Yes.

JUDGE DeBUSSCHERE: I ask, if you can speak up just a little bit, too, so we can hear you. We have you on a speaker phone.

THE WITNESS: Yes, I'm on a speakerphone as well, because with me is Mr. Carl Turner, who is an attorney for the Commissioner's Office.

JUDGE DeBUSSCHERE: Will he be there, is he there to listen or is he going to be advising you while you testify?

MR. TURNER: I'm primarily here to listen, Your Honor.

JUDGE DeBUSSCHERE: All right. Well, Mr. Turner, if you do say something, I would ask that you alert us what you are doing, okay?

MR. TURNER: I will.

JUDGE DeBUSSCHERE: Thank you.

Mr. Armstrong – Let's see. One other thing. Mr. Ogden, I understand you have to leave at 5:30 your time; is that correct?

THE WITNESS: Yes, it is.

JUDGE DeBUSSCHERE: What time do you have there?

THE WITNESS: 4:25.

JUDGE DeBUSSCHERE: You are at 4:25?

[2388] THE WITNESS: Approximately.

JUDGE DeBUSSCHERE: So it looks like you have about an hour and five minutes available to testify?

THE WITNESS: That would be correct.

JUDGE DeBUSSCHERE: Because of that, I'm going to limit the parties to how much time they have. So I will give Mr. Armstrong 20 minutes for direct; Mr. Bishin, 20 minutes for cross. Then, the panel members may want to ask you some questions, and I give them 20 minutes to ask you questions as well.

So go ahead, Mr. Armstrong.

MR. BISHIN: Just one moment. I want to make sure it's clear on the record that I object to this procedure, insofar as my right to cross-examine, my client's right to cross-examine has been curtailed.

JUDGE DeBUSSCHERE: Yes. Your objection is on the record. Thank you.

Go ahead, Mr. Armstrong.

DIRECT EXAMINATION

BY MR. ARMSTRONG:

Q Good afternoon, Mr. Ogden. Can you hear me okay?

A Uh, fairly well.

Q I'll try to speak up.

* * * *

[2399] cross-examination. Mr. Bishin?

CROSS-EXAMINATION

BY MR. BISHIN:

Q Mr. Ogden, good afternoon.

A Good afternoon.

Q First of all, Mr. Ogden, you don't have any personal knowledge of the LISTEN device that was purchased by Dr. Jeffrey Ames, do you?

A That's correct.

Q You don't know what labeling that device had on it; isn't that correct?

A That's correct.

Q And you don't know the specifications that it has; isn't that correct?

A That's correct.

Q Now, let's go talk about the Digital Conductance Meter for a Moment. You just testified unequivocally that if there were changes made to the LISTEN device, it would require another premarket notification and clearance, or did I misunderstand what you testified to?

A That's correct.

Q You are saying that any changes to a device that has been cleared requires a new clearance?

MR. ARMSTRONG: Asked and answered, [2400] objection.

JUDGE DeBUSSCHERE: Overruled.

A No, that's not what I'm saying. You could make minor changes to a device by changing the screws on the box, change some resistors, perhaps, in their circuits to make it perform in the same manner but more efficiently, and still not require a new premarket notification.

Typically, the trigger for acquiring a new premarket notification is you've changed the performance of the device in such a way that it now is outside the performance range that was cleared.

Q (By Mr. Bishin) Wait a minute. Now, Mr. Ogden, that isn't what the FDA says in its published documents, is it?

MR. ARMSTRONG: Objection. Your Honor, he is asking the witness for a legal conclusion, and you've already ruled that's not going to be allowed in this case.

JUDGE DeBUSSCHERE: Overruled.

Q (By Mr. Bishin) That's not what the FDA says in its published documents, is it?

MR. ARMSTRONG: Objection, again, Your Honor.

JUDGE DeBUSSCHERE: Overruled.

MR. ARMSTRONG: Which document that he's [2401] referring to? Web site, physical documents, legal documents from the Office of Compliance? It's vague. We don't know which documents he's referring to. The FDA is a giant organization. They have millions of pieces of paper. Which document is Mr. Bishin referring to in making this statement?

JUDGE DeBUSSCHERE: Overruled.

Do you remember the question, Mr. Ogden?

A Please repeat it.

Q (By Mr. Bishin) The question is, isn't it true, Mr. Ogden, what you stated is not true and that the FDA's publications do not state the criteria for a new, for a change in a device that has already been cleared?

A My answer to that would be that the FDA has a guidance document which specifically addresses whether a manufacturer should submit a 510(k) when they are changing their device.

Q That's right. And that document is called, that document is called, quote, Deciding when to submit a 510(k) for a change to an existing device, unquote. Isn't that correct?

A Yes.

Q All right. And in that device, they specifically say, don't they, that the key consideration, the key consideration is whether the change, quote, could [2402] significantly affect the safety or effectiveness of the device, unquote? Isn't that what it says?

A It says that, yes.

Q That's what it says. And in talking about the device, it says that the regulatory criteria statement of premarket notification must be submitted when the device is one that the person currently has in commercial distribution or is reintroduced into commercial distribution and is about to be significantly changed or modified in design, components, methods

of manufacture or intended use, the following constitutes significant changes or modifications that require a premarket notification. One, a change or modification of the device that could significantly affect the safety or effectiveness of, the device; e.g., a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Two, a major change or modification to the intended use of the device.

Isn't that what they say?

A Yes.

Q Okay. Now, you don't know whether this device that Dr. Ames purchased – First, let me strike that for a moment.

The FDA does not require a clearance, does it, of a [2403] device, simply because it changes its name; isn't that correct?

A That's correct, with the caveat that, as long as the name change does not imply a new indication for use or intended use.

Q As long as the labeling doesn't say that; isn't that right?

A Yes.

Q Okay. So that if the manufacturer of their DCM changed the name to listen or used that name as its brand name, that wouldn't require a new clearance for DCM, would it?

A Correct.

Q Now, secondly, if the manufacturer of the DCM decides to offer it with software that did not significantly change the, that did not raise any new issues of safety or effectiveness and which did not have any different labeling from the labeling that was approved by the FDA, that would not require any new clearance either, would it?

A That's correct, as long as there was no need for any clinical data to show substantial equivalence.

Q Okay, that's right. Now, when you deal with people who are seeking either clearances or approvals, do you ever, do you ever suggest to them or have you ever suggested to them changes in the way they make their application?

[2404] A Yes.

Q For example, when you get a premarket notification from a manufacturer and it has, maybe, a number of different uses on it, have you ever said, well, you know, we're not going to be able to clear that with those uses listed on the label, but if you take some of them off, then we might be able to clear it? Have you ever done that?

A Yes.

Q And in some of those situations, have you then cleared the device?

A Yes.

Q Okay, good. Now, have you ever had a situation where someone has come to you for premarket approval and you've told them something like, well, we can't give you a premarket approval right now because you just haven't gotten enough data for us yet, we need more clinical trials than this to do this, or you had some other reason, and so you said to them, but you know what you can do, if you want to get this on the market, you can change your labeling so that you have a labeling which indicates that it has the use of a predicate device, and we can give you a clearance to get it on the market, but you'll have to limit your labeling claims to the ones that are approved in the clearance. Have you ever [2405] done anything like that?

A Yes.

Q And that's something that – You are not the only one who's done that; isn't that correct?

A Correct.

Q I mean, that's part of the service function of the FDA's device division in working with and helping manufacturers who seem like reputable businessmen; isn't that right?

A Yes.

Q Now, are you familiar with the bone screws that have caused so much litigation in this country, bone-screw litigation that was – I can't remember the name of the company. Was it Accupath?

Did you deal with that in your division?

A It was dealt with in my division, yes, but not in my branch. So I'm only peripherally aware of the bone screws, which I believe are called pedicle screws?

Q That's exactly right. Those are the ones I had in mind.

So that was just something you talked about in the FDA maybe at lunch but you actually didn't officially have to deal with?

A Correct.

Q And those bone screws, they are the subject of that fairly recent United States Supreme Court case, [2406] *Buckman v. Plaintiffs' Legal Committee*? Do you remember that?

A I'm not aware of that case.

Q All right. Are you aware of the issue that was involved with regard to the bone screws that, originally, the manufacturer applied for, applied for a clearance for the bone screw as it was to be used as a pedicle screw in the spine, and the FDA turned them down? Do you remember that?

A Not specifically.

MR. ARMSTRONG: Objection, Your Honor, just to this line of questioning, on the relevance.

MR. BISHIN: Well, I'm done with it.

Just a moment. I'm not done with him.

How many minutes do I have, Your Honor?

JUDGE DeBUSSCHERE: Objection sustained, on the issue of bone screws.

MR. BISHIN: How many minutes do I have, Your Honor?

JUDGE DeBUSSCHERE: You have ten more minutes. That will be 2:00.

Q (By Mr. Bishin) I have ten pages of questions for you, Mr. Ogden, but it's not going to happen, obviously. So I have to pick and choose my best questions.

Now, any individual or entity can seek a clearance; [2407] isn't that right, Mr. Ogden?

A Yes.

Q Let's assume that an inventor seeks a clearance and he gets one from the PTA for a particular device. Are you still with me?

A Yes.

Q Okay. And then the inventor decides to assign his device to a company. Are you still with me?

A Yes.

Q Okay. And the company then manufactures the device and distributes it. That company does not

need to seek its own clearance for that device; isn't that right? It can rely on the inventor's clearance?

A That's correct.

Q Now, bear with me, please. The FDA, when it decides whether or not a, when it deals with a notion of intended use, unquote, quote, intended use, unquote, it deals, it tries to make the determination of the intended use of a device that's submitted to it as part of its general evaluation and approval process; isn't that correct?

A Yes.

Q And when it does that, it limits itself, does it not, to the use that is stated on the labeling that is submitted with the application; isn't that correct?

[2408] A I would change that around to say that the device is limited to the labeling for which it is approved, not when it's submitted.

Q The device is limited, the device cannot be marketed or promoted for any other use than the one on its label that's been approved; isn't that correct?

A Yes.

Q You look at labels, and then you approve the label; isn't that correct? When you approve the device, you are approving the label; isn't that correct?

A Yes.

Q If you don't like the label, you are not going to approve the device; isn't that correct?

A Yes.

Q But on the other hand, when the manufacturer submits a device to you and says that this is the use and the only use we're going to put on this label, you can't go beyond that and say, well, we're not going to give you the clearance or approval because we think that people are going to use it for something else; isn't that correct?

A Correct.

Q You are bound, just as the manufacturer is bound by what's on the label, you are bound by what's on the label, too. The statute specifically says that, doesn't [2409] it?

A Yes.

Q Now, Mr. Ogden, you've met with or talked to Mr. Armstrong how many times prior to this testimony that you are giving today?

MR. ARMSTRONG: Objection, Your Honor, relevance.

JUDGE DeBUSSCHERE: Goes to – It's relevant.

Go ahead and answer the question, Mr. Ogden.

A I believe, five or six times.

Q (By Mr. Bishin) You've spoken to him five or six times. Now, I tried to talk to you, didn't I?

A You left a message on my voice mail, yes.

Q Actually – We won't go into that. But I left a message, I say I left you eight messages. But you say you did receive a message of mine, didn't you?

A Yes.

Q And you did not call me back, did you?

A I did not.

Q So you've never spoken to me except when I was deposing you or when I'm examining you right now; isn't that correct?

A Yes.

Q But you have spoken to Mr. Armstrong five or six times

* * * *

[2412] Q And there's also something called an investigational device exemption; isn't that correct?

A Yes.

Q When you get any one of those things, that means you can market a device, isn't that right, or not the latter one, you can't market it, but you can send it in interstate commerce; isn't that correct?

A Right.

Q Now, when the FDA approves a 510(k) premarket notification, that is not, that does not mean that the – Well, let's say when it disapproves. Let's say when it disapproves. That doesn't mean that the device is not safe or effective for the intended use, does it?

A It means that agency has found the device to be not substantially equivalent to a predicate device, and therefore, does not go to market.

Q That's right. It has to be substantially equivalent to a device that's already on the market. It may be safe, it may be effective, but it's not substantially equivalent. And therefore, it's not entitled to a 510(k) clearance; isn't that correct?

A Yes.

Q Now, we get to a premarket approval. Those are the ones that require a lot of data and support; isn't that right?

[2413] A Typically, yes. Safety and efficacy.

Q You have to have, you have to make a strong showing to the FDA ordinarily, don't you, that there's efficacy and safety –

A Yes.

Q – to get one of those.

And sometimes, that can take years and years; isn't that true?

A Yes.

Q And those can be very expensive, can't they?

A That's what I hear. I don't have any personal knowledge of that.

Q They take a lot of the FDA's time, don't they?

A They do.

Q So they are expensive to us, the taxpayers; isn't that correct?

A Yes.

Q So there's business time involved, too.

Now, you turn down a premarket, when you refuse to give a premarket approval, that doesn't mean, does it, that the device is unsafe or ineffective necessarily, does it?

A We would turn it down based on the device having failed to be shown safe and effective for the intended use they were applying for.

[2414] Q Right. In other words, they haven't given you enough evidence yet for you to give them the right to go to market; isn't that right?

A That could be one scenario, yes.

Q Well, let's talk about that one scenario. Now, that can happen, and the manufacturer eventually or some other manufacturer eventually can get a

premarket approval by getting more information to the FDA; isn't that correct?

A That could happen, yes.

Q Or could be some scientific development which would make it kind of clear that the device is effective or is safe or something of that sort, and therefore, merely calling that to the attention, of the FDA might change its mind. That's a possible scenario, too, isn't it?

A Yes.

Q So in other words, the FDA, when it withholds its sanction to go to market, it's doing it in order to be, to be safe, but it doesn't necessarily mean that any device it doesn't permit to go to market isn't a good device or isn't effective. It simply means it hasn't met the criteria the FDA is letting down at this time or at that particular time for getting such an approval or clearance; isn't that correct?

A For that labeling.

Q For that labeling, that's right.

* * * *

[2419] ask about the hypothetical?

MR. BISHIN: Now, I'm forgetting what I wanted to ask about. One of the things I wanted to ask about is the hypothetical.

JUDGE DeBUSSCHERE: Go ahead.

RECROSS-EXAMINATION

BY MR. BISHIN:

Q First of all, what you said was that if the manufacturer was, even though they had a clearance that covered one use, they were only selling it for another use to, I don't know who, the same customers, that your understanding was that the compliance division would take, would want you, would want them to come in and seek another clearance. That's what you testified to, isn't it?

A Yes.

Q You don't know if the manufacturer of the device that Dr. Ames purchased was selling it to people for only one use, do you?

A I do not.

Q You don't know what claims the manufacturer of that device was making at the time that he sold that device to Dr. Ames, do you?

A Correct.

[2420] Q You don't know what that label looked like at that time; isn't that correct?

A Yes.

Q You don't know how Dr. Ames was using the device; isn't that correct?

A Correct.

Q Now, Mr. DeMarco told you not to speak to me. He didn't tell you not to speak to Mr. Armstrong; isn't that correct?

A Yes.

MR. BISHIN: I'll stop there, Your Honor.

JUDGE DeBUSSCHERE: Opportunity for panel members to ask questions.

Mr. Tennis, do you have any questions?

MR. TENNIS: Yes.

EXAMINATION BY THE PANEL

BY MR. TENNIS:

Q Hello, Mr. Ogden. First of all, a simple question. Everybody has been talking about labels. Is that something that's on a sticky thing you put on a device, or is that a term that's used in some of the literature that goes with the device?

A We use the term "labeling" in a broad sense. It means any written or voice information that accompanies the

* * * *

[2935] **STATE OF WASHINGTON**
**DEPARTMENT OF HEALTH**
**MEDICAL QUALITY ASSURANCE COMMISSION**

| | | |
|---|---|---|
| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | ) | **No. 02-06-A-1012MD**<br><br>Day 4 – PM |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

APPEARANCES

| | |
|---|---|
| Health Law Judge: | Arthur E. DeBusschere |
| For the Respondent: | WILLIAM R. BISHIN<br>Attorney at Law<br>701 Fifth Avenue, Suite 4040<br>Seattle, Washington 98104 |
| For the Department of Health: | KEITH D. ARMSTRONG<br>Assistant Attorney General<br>1125 Washington Street Southeast<br>Olympia, Washington 98504 |
| Commission Members Also Present: | Sunanda Uberoi, M.D.<br>Janice Paxton, PA-C<br>Cabell Tennis, J.D., Public Member |

Renton, Washington
Jauary 16, 2004

**Robert H. Lewis & Associates**
*Certified Court Reporters*
5113 Pacific Highway East, Suite #1
Fife, Washington 98424-2639
Tacoma: (253) 952-2030 * Toll Free: 1-877-952-2030
Reported by Robert H. Lewis CSR# 2441

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[2957] JUDGE DeBUSSCHERE: We're back on the record. Mr. Clark was testifying, I think they were finishing up questions. Mr. Bishin, do you wish to call Mr. Clark or have Dr. Ames testify?

MR. BISHIN: I think we have to let Dr. Martin testify.

JUDGE DeBUSSCHERE: Okay, Dr. Martin, and we'll have to excuse Mr. Clark, because otherwise I don't know how much time it will take for Mr. Clark, because we've scheduled Dr. Martin for one o'clock, so I think that's what we have to do. So we'll have to call you in your room I guess. Are we all ready to go?

JUDGE DeBUSSCHERE: Yes. Your next witness, Mr. Bishin.

MR. BISHIN: Dr. David Martin, have a seat right there, Dr. Martin.

JUDGE DeBUSSCHERE: Would the court reporter swear this witness in.

* * * *

DR. DAVID MARTIN,

having been first duly sworn by the Notary, testified as follows:

JUDGE DeBUSSCHERE: Can you tell us your full name.

THE WITNESS: David Reed Martin.

JUDGE DeBUSSCHERE: And it's M-a-r-t-i-n?

[2938] THE WITNESS: That's correct.

JUDGE DeBUSSCHERE: Your witness, Mr. Bishin.

## EXAMINATION

BY MR. BISHIN:

Q Dr. Martin, it would not be impolite for you to not look at me and talk to me when I'm asking you questions, but instead talk to the panel and the presiding officer because they're the ones who have to really hear. So as unnatural as that may seem, would you try your best to talk in that direction; thank you.

Would you state your occupation, please?

A I'm a family physician and an acupuncturist.

Q An acupuncturist. And can you describe kind of generally the kind of practice you have, a little bit more elaborately so we understand kind of the details of it?

A I currently have a private practice in Seattle focused on, primarily on constitutional acupuncture; there's a lineage of acupuncture called thigh element acupuncture and I see usually eight to 10 people a day for anywhere from 45 minutes to two hours each, working with the energetic constitution of the individuals.

People come for basically the whole variety of Western medically trained reasons, although usually not for very acute causes that would more likely take them into an [2939] emergency room.

Q Okay. Do you find yourself involved with patients who have allergies?

A I certainly do.

Q Do you ever treat patients for allergies?

A I do.

Q Are you familiar with the general conventional medicine with respect to allergies?

A I'm familiar, yes.

Q And does conventional medicine, conventional approach to allergies, does it differ in significant respects from the approach that you have with respect to allergies?

A Yes. The entire framework that is used to treat allergies in acupuncture is different from Western medicine.

Q I'm going to go into that in a moment, but I just wanted to have a topic heading for this examination. Would you please give us your entire educational experience; where you went to school after secondary school and what degrees you received, what formal training you had; would you tell us that?

A Yes. I went to college at Dartmouth College and majored in math, physics, and engineering; did a year of graduate study at the Thayer School of Engineering at Dartmouth College, primarily focusing on computer [2940] architecture and theoretical physics prior to going to the medical school program at Harvard University, joint program between Harvard and M.I.T. for people with strong quantitative science backgrounds; graduated from the medical program at

Harvard Medical School in 1983 and attended three years of family medicine residency at University of Oregon Health Sciences Center; and then did two years of the Robert Wood Johnson Fellowship in the faculty at the University of Washington, Seattle.

Subsequently in 1994, '95, and '96, I trained in acupuncture at the Wu Hsing Toe School in an apprenticeship role in Seattle, graduated from there and took the national boards in acupuncture just in 2001. Mainly because some people who look at medical doctors practicing acupuncture from the acupuncture field don't necessarily think they have any credentials.

Q So your M.D. is from Harvard then?

A That's correct.

Q And do you have any informal training of any kind that supplements your formal education; any other kinds of courses that you've taken in specific fields of any kind?

A I've taken, you know, I do what would be the equivalent of continuing education, usually at least a week or two a year in observing senior acupuncturists in a particular lineage of acupuncture; and I've over recent

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[2960] Q And when you treat them how do you do it?

A In the same manner that I described in the example. I look at their constitution and I treat them based on their constitution; and if there are specific areas they are having allergies in, such as allergic rhinitis, they may get specific symptom-oriented points done for those. But in the way that I'm treating them to cure their allergies, is the way that I described.

Q In the field, in the broad field of acupuncture, do acupuncturists, do the, does a respectable opinion in acupuncture areas believe that allergies are something acupuncturists are competent to treat?

A I'm not aware of allergies being treated, being studied in any large studies as a group. Allergic rhinitis, for example, is one area that has been studied and is, you know, recognized by the World Health Organization as being one of the areas that acupuncture is involved in treating in individuals. Asthma, not really specifically allergy-related asthma, but asthma as a whole is also recognized as another area that acupuncture is useful in treating.

You know, as with Western medicine, there are many areas that acupuncture is used for that there have not yet been randomized control double-blind studies done for and there's some reason to believe that such studies don't [2961] necessarily have the same applicability in a medicine based on energetics. The same utility I would say, in medicine based on energetics as they do in Western medicine because of

the effects of the consciousness of the practitioners and the outcome of the studies.

Q I'd like to go into that a second, but that wasn't my question. My question was, not does Western science accept acupuncture for allergies, but does acupuncture accept acupuncture for allergies?

A Acupuncture accepts acupuncture for allergies. Now again, according to the different lineages there are different, some lineages have very little to do with allergies and other lineages have a lot to do with allergies and will treat them and will successfully.

I can think of many, many examples of acupuncture that is useful for treating allergies; so from my perspective, yes.

Q I'd like to get back to something –

MS. PAXTON: Mr. Bishin, can I just ask one question about a definition; lineages. How are you using that term?

A Just that the way acupuncture has been passed down over the years was really for thousands of years in small groups, in families and there are kind of different perspectives and different aspects that are developed in

* * * *

[2963] not deal with these same levels of existence as Asian medicine on which acupuncture is based, on

which acupuncture represents; is that what you're saying?

A Well, in my understanding Western medicine, most of Western medicine is biomedicine, it's based on material reality; there are aspects of medicine, psychology, psychiatry, which bring in other levels, you know.

There are kind of psychosocial levels brought in, but that still occurs within a framework where it's almost understood implicitly that the mind, if you will, is generated by the brain and it all has a material basis and that's not the point of view from the East where consciousness is actually more fundamental than the material level of reality.

Q Could you elaborate a little bit more on what sense is consciousness more fundamental than the material level?

A When I say it's more fundamental, I mean that in the particular world view that acupuncture is based on and I'll give a more concrete example of this, but that treating things on the energy level can heal things on the physical level.

And so the physical level in some sense is dependent on, or doesn't determine the energy level the way the energy level can determine the physical level, and in my early experience in acupuncture I was shocked at times

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[2968] used where a glass container is placed on the skin and it's burned inside it to create a vacuum; bleeding can be used, a variety of different –

Q And is acupressure related to acupuncture?

A Yes. It uses the same points, basically stimulates the points with a non-invasive means rather than a needle.

Q And you say non-invasive means, what kinds of means are we talking about?

A Just pressure and often an amount of motion or pressure on the point.

Q Is it possible to do acupressure with something like what's in front of you; do you recognize that?

A Certainly.

MR. ARMSTRONG: Objection, vague.

JUDGE DeBUSSCHERE: The question's vague; could you please have the witness –

Q (By Mr. Bishin) Would you please describe what's in front of you, the device?

A It's not something that I'm familiar with as a specific device, although it appears to me that it's along the line of devices that provide a mechanical level of stimulation to these points which are then placed on points on the body to give mechanical stimulation to those points.

Q Would you just briefly describe for the record, what it is you're holding in your hand?

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[2970] system.

A Yes. You know, I will often use some acupressure in my treatment if the point doesn't need the amount of stimulation that acupuncture will give it; acupressure is useful. I often use acupressure with children who don't need very much stimulation. So the same fundamental view is underlying acupressure as well as acupuncture.

Q Now, in the acupuncture community, is acupressure ever used to treat allergies?

A Yes.

Q Are you familiar with any schools or methods that do treat allergies with acupressure?

A Several different schools, there's NAET, Nembudripad Allergy Elimination Technique; there's TAT, Tapas Acupressure Technique; there are others, Allergy Relief System, ARS is another technique.

Q These all use acupressure for this purpose?

A Right.

Q And are these regarded as respectable among the acupressure/acupuncture community?

MR. ARMSTRONG: Objection; respectable.

MR. BISHIN: I'll say there is a doctrine of law, Your Honor, that says respectable minority, I don't want to get into the majority because there aren't any, you judge by the standards of that respectable minority, that's [2971] why I'm asking with respect to minorities.

JUDGE DeBUSSCHERE: Overruled.

MR. BISHIN: Would you read back the last question, please?

THE REPORTER: (Complying)

A There are certainly groups, again there are many lineages of acupuncturists and some acupuncturists would use modalities like this. And there are many people practicing these particular modes of allergy treatment within the acupuncture community as a whole.

And from my particular personal perspective, I've certainly seen clients of mine get treated with these methods and get relief from their allergies, sometimes in ways that I am clear that it came from the treatment.

For example, I had one, about 33-year-old woman, who had had G.I. distress and skin allergies for years and had been through Western medical treatment for years; had been on elimination diets fairly strict, keeping off all wheat, all dairy, a variety of other things I can't recall at the moment; and she went into NAET treatment and over the course of a

year all of her allergies completely resolved. She now eats whatever she wants to and has no problems.

Q (By Mr. Bishin) The types of people that practice NAET, do they have the standard kinds of certification and [2972] credentials that are considered to be respectable or desirable in the acupuncture community?

A Because NAET is an acupressure technique it doesn't necessarily require the licensing that is required of acupuncturists. It does require that people be, as I understand it, and I'm not an expert on this, but as I understand it NAET training is open to people who are licensed in one way or another to treat people for illnesses. And there is a set of courses that people go through at NAET and I think there's an ongoing education requirement to be considered a practicer of NAET or registered practitioner, that kind of thing.

So there is a training protocol for it and the acupuncturists who practice it are certified as acupuncturists by means of the way that they got there in the first place.

Q So the types of people that practice it, though, are there among those people, people who have credentials that are generally recognized by the, even by the medical community but certainly by the acupuncture community?

A Yes.

Q For example, do physicians practice NAET?

A I imagine that they do; you know, you're asking me a little bit more than I'm familiar with about the NAET practitioner group. Most of the people that I know that [2973] practice NAET are acupuncturists, but I know that chiropractors practice it and I know that doctors can practice it. I just, to this point in my acquaintance with people, haven't found specific doctors that practice it.

Q Now, how would you compare the success of acupuncture and acupressure in treating allergies with the success of Western medicine?

A Could you ask me a more specific question?

Q I was hoping you would break it down. First of all, let me, are there significant number in your opinion of instances and situations in which acupuncture or acupressure is able to get positive results for people who are suffering from allergies when Western medicine is unable to deliver such results?

A Yes.

Q Can you tell us a little bit about that, more general things?

A Well, you know, the options within Western medicine for treating allergies are few. There are a number of methods for symptomatically reducing the effects of allergies.

There are for some types of allergies, such as allergic rhinitis and allergy-related asthma, there are immunotherapy protocols that can be used in

Western medicine, but immunotherapy protocols are not particularly [2974] helpful for food-related allergies or food-intolerance as far as we know.

And so there are often not a lot of ways to cure allergies from the Western medical perspective. And even when using immunotherapy there are risks, there are, you know, dozens of people have died over the last few decades due to scratch tests and due to immunotherapy applications in Western medicine.

From the acupuncture perspective, you know, what's bothering the person that is looked at as an allergy from the Western perspective is seen as a pattern that isn't necessarily labeled as an allergy, and often the individual can be brought into an equilibrium where that is not, doesn't bother them nearly as much from the acupuncture perspective, and with very little side effects, a little bit, of an ouch with a needle.

Q So the side effects, are there any situations in which death has occurred because of the acupuncture or acupressure treatment of allergies?

A None that I'm aware of. They are very rare in acupuncture as a whole if a needle that is too long is stuck in the wrong place, in the lung for example, it can cause a pneumothorax which can be, can lead to death if appropriate help and recognition of the syndrome is not, but that's very, very, very rare. I've never heard of it

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[2976] there are RASP tests that look at the antibodies in the blood stream.

But, you know, getting a skin test and even more so with the RASP test, the standard directive in a medical textbook would be that you can't trust them whether they're positive or whether they're negative. A RASP test is at best confirmatory to some degree if you're considering there's an allergy in some area. There are many, many false positives, there are false negatives, they just cannot be counted on as a diagnostic method, and so they're available and they're part of the Western medical system, but they're not very accurate.

Q Let me ask you, are you familiar with kinesiology or muscle testing?

A Only secondarily, it's not part of my practice, I've never studied it.

Q But in the course of, is it something that's done by acupuncturists as part of –

A It's not really part of acupuncture as a whole, but it's a part of alternative medicine. I'm familiar with it in my wider familiarity with people who practice alternative medicine. I know chiropractors who use it, some naturopaths who use it, you know, it's integrated often into methods like NAET that are used by acupuncturists, but it's not a specific part of [2977] acupuncture.

Q In the alternative world is it something that is considered to be a respectable device by a significant number of people?

MR. ARMSTRONG: Objection; if I understand counsel, he's saying kinesiology is a device.

JUDGE DeBUSSCHERE: Objection sustained; can you clarify your question?

Q (By Mr. Bishin) I won't characterize it as a device or a process or anything. Is muscle testing or kinesiology considered to be among a significant number of people in alternative medicine a useful phenomenon?

A Well, I would say two things; one is based on the fact that a considerable number of people in alternative medicine use it, that it must be considered useful.

It, in my experience, is useful in the hands of some individuals and I've seen people who seem to be very effective in the treatment they give based on kinesiology, but I can't give you any literature kind of overview or assessment of the field as a whole other than it is definitely respected by people when it's in the hands of certain people.

Q Now, you were talking a little bit near the beginning of this examination about whether or not the most typical

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[2985] there are a possibility of things like that.

It also mentions that there are times in the process of treatment with acupuncture when the symptoms the individual is having may flare up and be worse than they were previously.

Q One last question. You mentioned the term EDS, electrodermal screening?

A Yes.

Q Are you aware of –

A I think I mentioned electrodermal device.

Q Device?

A Yes.

Q Do you know if electrodermal device can diagnose an allergy in the skin?

A I don't know the answer to that. I actually did some research on that for this particular occasion and the last time that the Clinics of North America put together a panel statement, entire issue evaluating allergy diagnosis and treatment, which was in 1995, they said that electrodermal screening was as yet untested.

And when I did a Medline search I found nine or 10 papers that came up with the words electrodermal allergies over the last nine years, and there are some of those that report that in double-blinded trials they are successful in diagnosing allergies, and there were

some of [2986] them that said there is no effect; and this goes back to this example about the issues of the mind and the problem with doing the research that we were talking about.

And like in many areas early studies don't all tend to go the same direction; so, you know, I think my assessment would be in some peoples' hands these work.

Q Okay. The second part of my question is, would electrodermal screening, would that cure an allergy based on your experience and knowledge?

A Well, my understanding of the term electrodermal screening isn't a diagnostic treatment.

Q Okay, so it's not a treatment; it's a diagnostic tool?

A Well, electrodermal screening particularly is screening for something and if it's electrodermal allergy screening you're talking about screening for allergies.

MR. ARMSTRONG: That's all; thank you, Doctor.

JUDGE DeBUSSCHERE: Questions from the panel members; Mr. Tennis?

**EXAMINATION**

BY MR. TENNIS:

Q You said at some point that, so we're dealing with the difficulty of the two worlds you live in, the Harvard M.D. world and the acupuncture world, that you changed the sign on your office; did I hear you correctly?

[2987] A Oh, what I was referring to is in my medical practice, at that time at Group Health there was a little sign up saying that I'm not in the office on Mondays because I'm starting up an acupuncture practice; so a lot of people wanted to come because of that and I took that sign out of there because it just wasn't the best way to start working with people.

Q Okay, I thought you had an acupuncturist in sign or something like that.

A No, they were separate offices.

Q And you were in Group Health but now you're in private practice?

A That's, right.

Q Colleagues or just by yourself?

A In the physical location that I'm at, there's a naturopath and a Ph.D. counselor and I have people coming through for training, that kind of thing, so there are colleagues there but I'm the only five-element acupuncturist full-time.

Q Do you use any devices in your treatments or practice?

A I don't.

MR. TENNIS: That's all I have.

JUDGE DeBUSSCHERE: Dr. Uberoi?

A (Continuing) I mean other than needles and moxa; the needles got off the experimental device a few years ago for [2988] acupuncture, the FDA kept them as an experimental device for I don't know, 10 years or so.

JUDGE DeBUSSCHERE: Dr. Uberoi, do you have any questions?

DR. UBEROI: Just give me a few seconds.

JUDGE DeBUSSCHERE: I'll ask Ms. Paxton and then you can come back.

**EXAMINATION**

BY MS. PAXTON:

Q Dr. Martin, I'm not sure because of your previous response about kinesiology if you're able to answer this question, but I'm going to shoot it towards you and see what you can do with it. We've been told that there's muscle testing involved with allergy testing in this case to find out what actual food in this case rather than a pollen or grass or whatever is the culprit in somebody's allergy?

A Right.

Q And that there is a way of delivering that message to the person, to the patient in conjunction with pressing down on an arm and resistance. Are you with me so far?

A Yes.

Q In this case we have been dealing with this machine which is to your left, which without going through all the what is it and who is it and all that, that its to your

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[2993] **EXAMINATION**

BY DR. UBEROI:

Q One is that would you treat somebody with DR-5 element acupuncture schooling just based on a RASP test, RASP test on like egg allergy six, the person says I don't like eggs but I keep eating them and I don't have any symptoms; I understand you might want to treat the patient anyway for other things and balance.

A I, generally when I talk with people on the phone about whatever they're coming in for, even if it's something I know is very amenable to acupuncture, I ask them generally speaking if this is just a bother and they just want the symptom to go away or whether they're really looking at this as having something to do with their overall balance and

lifestyle and they're really willing to work on another level about what is this symptom, why is it coming.

From my understanding, a RASP test showing an egg allergy with no symptoms needs no treatment by anybody. And the only reason that I would treat someone like that is if they really were in a place of wanting to get constitutional acupuncture for its preventative benefits rather than treating them.

Q Right, okay; one more question. When you said treatment you mean – I wouldn't want to use the word energy

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[2519] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

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| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | Docket No.<br>02-06-A-1012MD<br><br>Day 3 |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR the Department OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

**COMMISSION MEMBERS PRESENT**

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.,
Public Member

Renton, Washington
January 15, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[2692] afternoon break. It's now 3:55 p.m., and the Respondent is presenting his case in chief.

Let's go off the record while I dial the number.

(Off the record.)

JUDGE DeBUSSCHERE: This is Health Law Judge Arthur E. DeBusschere, and this is a matter before the Medical Quality Assurance Commission. Mr. Bishin has identified you as a witness, okay?

PATIENT 2: Yes.

JUDGE DeBUSSCHERE: All right. Let me briefly give you more introduction so you understand who's calling you.

My name is Arthur E. DeBusschere. I'm the presiding officer, health law judge presiding over this hearing. This hearing is being conducted at the Renton Holiday Inn select hotel in one of the conference rooms.

This conference room, the hearing is being recorded by a court reporter, so testimony that you will be giving will be recorded by a court reporter. There are commission, Medical Quality Assurance Commission members here, three commission members,

Mr. Tennis, Doctor Uberoi and Ms. Paxton are commission members that are hearing this.

[2693] The Assistant Attorney General, Mr. Keith Armstrong, is here representing the Department of Health, and Mr. Bishin is here with Doctor Ames, representing, Mr. Bishin is an attorney representing Doctor Ames, who is also present.

This is a public hearing, so there are two or three other individuals in the room.

Patient 2, I'll ask the court reporter to swear you in.

Can you hear me okay? I should have asked you that first. Can you hear me okay?

PATIENT 2: Yes, I can.

JUDGE DeBUSSCHERE: If you can speak up the most you can, I would appreciate it.

PATIENT 2: Okay.

JUDGE DeBUSSCHERE: Will the court reporter swear this witness in.

* * * *

PATIENT 2: Having been first duly sworn, testified as follows:

JUDGE DeBUSSCHERE: Could you tell us your full name.

THE WITNESS: Patient 2.

[2694] JUDGE DeBUSSCHERE: And your last name is spelled Patient 2?

THE WITNESS: Right.

JUDGE DeBUSSCHERE: Patient 2, your testimony is being transcribed by a court reporter. What I will ask the court reporter to do, because of the Health Care Information Act, and you have been identified as a patient, is that Mr. Bishin and Mr. Armstrong and maybe the panel members who might ask you questions, can refer to you as Patient 2, but the court reporter will transcribe your name as Patient Number 2.

THE WITNESS: Okay.

JUDGE DeBUSSCHERE: So the record will reflect Patient Number 2 testifying, but you'll be identified as Patient 2 and testify as Patient 2.

Mr. Bishin, your witness.

* * * *

DIRECT EXAMINATION

*BY MR. BISHIN*:

Q. Good afternoon, Patient 2.

A. Good afternoon.

Q. Can you hear me?

A. Yes, I can.

Q. Patient 2, can you tell us where you live?

[2695] A. I'm sorry, I can't hear you as well as I thought I could.

Q. I'm going to move a little bit closer, so I'm more in line with the speaker phone. Can you hear me better?

A. Yes, I can.

Q. Patient 2, where is your place of residence?

A. Richland, Washington, address 2612 Saddle Way.

Q. And what is your employment?

A. I am employed by Duratek Hanford Company as quality assurance manager of the project Hanford Management Contract on behalf of Fluor Hanford.

Q. What does that position entail?

A. The position entails managing the overall quality assurance program for this prime contract at the nuclear facility, as well as performing, managing the performing arts, assessments of ongoing work activities.

Q. Can you tell us a little bit more about what quality you are assuring?

A. We are assuring quality in accordance with MGM 830 Subpart A, which are the Nuclear Safety Quality Assurance Requirements, a federal regulation.

Q. Okay, and how long have you been doing this [2696] job?

A. This current job approximately five years, but I have 20 years experience at Hanford, 32 years overall in quality assurance.

Q. Thank you. Approximately how many employees of your company report to you?

A. Nine.

Q. Now, are you familiar with Doctor Geoffrey Ames?

A. Yes, I am.

Q. Can you tell us how it came about that you became familiar with him?

A. It was actually my wife that was looking for a new doctor, and Doctor Ames was just opening his practice in Richland there. She called and made an appointment. She liked him, and most importantly, she liked the fact she had finally found a doctor that was willing to LISTEN to her, and he became our family physician.

Q. Okay. Now, in the course of your relationship with Doctor Ames, have you ever consulted him with respect to any allergies of any kind?

A. Yes, I have. I had a couple of significant allergies one of which was to tomatoes, and the [2697] reaction I was having to tomatoes was that it would cut off my windpipe and would cause me to go

through a series of rather severe throat clearing exercises until I could breathe again.

The other allergy was an allergy that turned out to be to sugar. I had no idea what that one was until I went to Doctor Ames, but I was getting very severe headaches that I noticed after eating certain foods.

Q. Okay, and did Doctor Ames treat you for the allergy that was connected to tomatoes?

A. Yes.

Q. All right, and do you know what the result was?

A. The result was very positive. After the treatment I have been able to eat tomatoes ever since.

Q. And you have never had any symptoms?

A. No side effects.

Q. I burden of proof? [sic]

A. I said I have been able to eat tomatoes ever since the treatment, with no side effects.

Q. So the symptoms that you described before, disappeared entirely?

A. I'm sorry.

[2698] Q. I said are you saying that the symptoms that you just described about your throat disappeared entirely?

A. Yes, that's true.

Q. Now, with respect to the sugar, were you treated for that?

A. Yes, I was.

Q. All right, and let me ask you this: what was the treatment that was employed for the tomatoes?

A. The treatment involved Doctor Ames using the machine, and I'm sorry, I don't recall the name of the machine, but it involved me holding a probe in one hand, and Doctor Ames would give me a strength test which consisted of me lying on my back with my left Armstrong up in the air, and he would apply pressure to my arm.

If it was a negative reaction, I was able to resist the pressure very easily, however if it was a positive reaction, I was unable to resist, and my arm would fall.

Q. Did he then treat you after that?

A. Yes, he did.

Q. What was the nature of the treatment?

A. Again, I don't remember the name of the apparatus, but it involved a technique of him using [2699] the machine going up and down my spine, and then he would massage certain areas on my hands and feet.

Q. And I'll come back to the device for a moment a little bit later on. With regard to the sugar allergy, did he treat you for that, also?

A. Yes, he did, and that was most interesting because we didn't have any idea what could be causing it, so he actually tried multiple causes, and all kinds of different foods, and I was able to resist the strength portion of the examination on everything except sugar. When we finally tested for sugar, my Armstrong collapsed. It was just incredible.

Q. All right, I was going to wait to talk about the machine, but since you have said it again, when your arm collapsed, did you make an effort to resist?

A. Absolutely. Absolutely. It had become sort of a challenge, you know, because he asked you to give him strength, so you really tense your arm up, and there is quite a bit of strength exerted in that, and that's what makes it more amazing, when you do find the thing that you're allergic to, your resistance is almost completely gone.

Q. Let me ask you this: Did he do this procedure on your back once he –

[2700] A. Yes.

Q. I burden of proof [sic], in connection with the hypothesis that you had a sugar allergy?

A. Yes.

Q. He did, all right. Did you have any evidence that it had any effect?

A. Yes, he tested me again, as he did before, and I was able to resist it completely.

Q. What happened to your symptoms, though, was there any affect on your symptoms?

A. The symptoms have disappeared. I'm now able to eat sugar, which might be unfortunate, but, yeah, I can eat sugar just fine now.

Q. Okay, and let me just make sure for the record to clarify this. With respect to the tomato allergy, when he tested you, did he test you with that same muscle testing procedure, with testing your muscle and having you hold the probe, and then testing your muscle again?

A. Yes.

Q. And you became weak when he typed in tomato; is that what you're saying?

A. That's correct.

MR. BISHIN: That's all I have, Your Honor.

* * * *

[2707] A. I do not.

Q. Patient 2, have you ever been diagnosed with sugar allergy or tomato allergy before Doctor Ames?

A. No, sir.

Q. Have you had any treatment by another health care provider, after Doctor Ames treated you for sugar and tomato?

A. Not for allergies.

Q. Have you ever had allergies come up on any other test by another profession?

A. No.

Q. You mentioned – let me ask you a question about, you mentioned that there were multiple exams for the sugar?

A. I'm sorry, I missed that. Would you repeat it, please?

Q. You mentioned that you had multiple exams to determine that it was a sugar allergy that you had; is that correct?

A. Yes. Yes, he tried a whole variety of different kinds of foods on me before we arrived at sugar.

Q. So he would type in a different food, and then do the testing, and he would go to another food and then do the testing, is that the procedure?

[2708] A. Yes, exactly.

Q. Thank you, that's all I have.

JUDGE DeBUSSCHERE: Redirect on the questions asked.

Mr. Bishin, do you have any additional questions?

MR. BISHIN: Yes.

REDIRECT EXAMINATION

*BY MR. BISHIN*:

Q. I have a couple of questions, Patient 2. I just want to make sure for the record, because I'm not sure what the answer turned out to be.

As I understand your testimony the testing involved muscle testing and holding this probe in your hand, and Doctor Ames typing something into a computer; is that right?

A. Yes.

Q. And the treatment involved this procedure on your back?

A. Yes.

Q. Okay, and when Doctor Ames, when you came to Doctor Ames with the food allergy, did he take a history from you, did he ask you about your symptoms, and anything else?

A. Absolutely.

[2709] MR. ARMSTRONG: What was that answer? I didn't hear you.

JUDGE DeBUSSCHERE: Absolutely.

Q. How long after you started seeing Doctor Ames did you come to him for the tomato allergy?

A. Gosh. You're asking an old man a memory question here. I have been going to Doctor Ames for approximately 10 years, my wife and I. My tomato

allergy probably showed itself somewhere around five or six years ago.

Q. Okay. So had Doctor Ames taken histories of you before you came to him with the tomato allergy?

A. Yes.

Q. Do you know if he had a substantial chart for you prior to the tomato allergy?

A. My file there is pretty thick, yes.

Q. Okay, I think that's all I have. Thank you very much. We now have to hear from the Panel.

JUDGE DeBUSSCHERE: Patient 2, this is Health Law JUDGE DeBUSSCHERE Art DeBusschere. The Panel members may want to ask you some questions. I'll ask each of them individually if they do.

Mr. Tennis, do you have any question of Patient 2?

MR. TENNIS: No, thank you.

* * * *

[2714] tomatoes were cooked tomato or a raw tomato, that you would have that reaction of swelling or shortness of breath?

A. No. I would have the same reaction. It was a closing of my throat, sort of gagging and throat clearing rather violently, more violently than I liked it.

Q. Okay, and how soon after you had your treatment for the sugar allergy, did you try sugar?

A. I wasn't as anxious after that one, because the headaches really hurt, so I would try little portions, and then you know there is so many foods that contain sugar, it's almost impossible to avoid them unless you stay away altogether.

I was picking up normal sugars in regular foods, and stuff like that, and it was probably within 24 hours that I decided to try a bite of a cookie, something I knew had a lot of sugar in it, and I had no reaction.

Q. Is there anything else, besides your sugar allergy and tomato allergy, that you have an allergy to?

A. I'm not aware of any allergies right now.

Q. Thank you very, much.

JUDGE DeBUSSCHERE: Patient 2, there may

* * * *

[2805] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

| | |
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| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | Docket No.<br>02-06-A-1012MD<br><br>DAY 4 – A.M. |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

[2838] Go ahead, Mr. Bishin.

JUDGE DeBUSSCHERE: We have to swear the witness in, and would you tell us your full name, please?

THE WITNESS: James Hoyt Clark.

JUDGE DeBUSSCHERE: Would you swear in the witness.

* * * *

*JAMES H. CLARK*,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

*BY MR. BISHIN*:

Q. Mr. Clark, where do you live?

A. I live in Linden, Utah.

JUDGE DeBUSSCHERE: Excuse me. Can you speak up, and face a little more this direction so I can hear you. I'm a little bit of hard of hearing.

A. I live in Linden, Utah.

Q. You don't have to talk to me, even though I'm asking the questions. Talk to the Panel. They're the ones that have to hear you. If I don't hear you, I won't be bashful.

A. Okay.

Q. You live in Linden, Utah did you say?

[2839] A. Yes.

Q. What is your occupation?

A. I am a bioengineer that does development work and software programming.

Q. A bioengineer that does what?

A. Software development.

Q. Do you have a company?

A. Yes, I do.

Q. What is the name of the company?

A. I have a company Health Dimensions International. It's an R & D company.

Then I have Star Tech Health Service. That's a distribution company.

Q. What's an R & D company?

A. Research and development.

Q. What does that company do?

A. That company does software programming for systems and computers in the alternative health field.

Q. And Star Tech Health, what is the nature of its business?

A. Star Tech Health is a manufacturer and distributor in training and service of alternative health instruments.

Q. What kinds of devices does it have on the [2840] market at the present time?

A. Primarily Computerized Electrodermal Screening Devices.

Q. What is a computerized Electrodermal Screening Device?

A. It's a device that is used in alternative health care to take galvanic skin response measurements.

Q. Okay. Now, galvanic skin response, can you tell us briefly what that is; is that pretty much what Doctor Sherman testified to the other day?

A. Yes, it was.

Q. Can you briefly remind us what a galvanic skin response device is?

A. The galvanic skin response device is an ohmmeter. It is calibrated to the specifics of what you're measuring, in this case the skin. It puts a very small current through the body and then measures the resistance of the electrons as they flow through.

Q. Now, the device that your company makes, can you tell us, Doctor, are there more than one model?

A. Yes. There are a number of models, the Orion, the Pegasus and the Mira.

Q. Those are the names of the three models?

A. Yes.

* * * *

[2845] A. They're device listings, the device listings that we submitted to the FDA.

Q. And those device listings are for what?

A. The Orion, Pegasus, Mira.

Q. Now, do these devices indicate that they are relying on the Digital Conductance Meter Clearance?

A. Yes, they do.

Q. Where do they do that?

A. In the proprietary name, line, Box 9 on the device listing form.

Q. Okay. Now what does the, what was the response of the FDA to your sending in this device listing indicating these devices were all digital conductance meters under the classification under HCC?

A. The FDA responded that they already had the listings, and did not need this information.

Q. Okay. Now, Mr. Clark, I'd like to go into your background a little bit, if we may. Can you tell us what your education is after secondary school, please.

A. Okay. I attended Trinity University in San Antonio, Texas, and for a year was in physics. I then transferred to Texas A & M University, and graduated in 1973 in bioengineering. I conducted [2846] research while I was there also. Then I went to the University of Texas Medical Branch in Galveston, Texas.

There I attended studies in medical biochemistry. I found while I was there that I didn't like test tubes, I liked devices, and I went and worked in Houston at the medical center there at the speech and hearing institute, developing information for autistic children while there.

I then returned to Texas A & M, and took a few classes there. Soon after that, after finishing those

classes, I went to Utah and I was able to attend Brigham Young University.

While I was there I got training as an emergency medical technician.

I received a Master's Degree in exercise physiology and a minor in digital electronics. I graduated with a Master's Degree in 1978.

Q. Okay. Is that the extent of your formal education?

A. I also returned to Texas A & M and took physiology from the vet school while studying hyperbaric medicine.

Q. So that would be the extent of your formal education, is that correct?

[2847] A. Yes.

Q. What about your informal education?

A. I have attended a number of classes where I learned about microprocessors and how to use them.

Q. When did you first become involved with galvanic skin response devices?

A. In 1978.

Q. Can you tell us a little bit about how that happened?

A. After graduating with a Master's Degree I was involved with some colleagues in developing courses for microprocessor training.

Microprocessors were a new concept at the time, and one of the people that I was working with met some businessmen that were bringing in Dermatron, a German electrodermal skin device, importing them into the United States, and they wanted to have the device computerized.

The German manufacturer was not interested in computerizing it. They had been making their dermatone for 20 years and selling them around the world, and the idea of computerizing was not interesting for them.

I was asked, because of my background, if I could computerize the device, and that's when I [2848] started on the development.

Q. What was that year again?

A. In 1978.

Q. Since that time how much of your professional or business time has been spent dealing with galvanic skin response devices?

A. Almost the entire time, 26 years.

Q. So for 26 years you have been in this particular area; is that right?

A. Yes.

Q. During that time did you become familiar with the industry, is there an industry of galvanic skin response devices?

A. Yes.

Q. Did you become familiar with the computerized types of galvanic skin response devices?

A. Yes. I'm considered the father of Computerized Electrodermal Screening.

Q. Why is that?

A. Because I was the first one to computerize it, some people out there that have done major publications in alternative health, gave me that title.

Q. Did you start developing your own computerized galvanic skin response devices?

[2849] A. Yes, I did.

Q. Let me ask you, you testified that the – let me ask you this first: Have you been qualified as an expert on computerized galvanic skin response devices?

A. Yes.

Q. By whom?

A. I was an expert witness for a trial in South Dakota before the state court there, and I also was a witness for an educational board in, chiropractic board in Minnesota.

Q. Have you had occasion to observe what goes on in the market for GSR devices, if I may call them that?

A. Yes, I have, worldwide.

Q. Have you traveled outside the United States on business related to galvanic skin response devices?

A. Yes, I have.

Q. How often have you done that?

A. A couple of times a year.

Q. Let me ask you this. About how many manufacturers are there of galvanic skin response devices that engage in the kinds of alternative, that design their products for alternative health care [2850] uses in the United States, would you say?

A. They are probably about 20 to 30 major manufacturers.

Q. And they all manufacture and distribute this kind of device in the United States?

A. I would say this kind of, yes.

Q. And how about outside the United States, any idea how many manufacturers there are of these devices?

A. There are a number of German and Russian and French manufacturers.

Q. And let me ask you this: These devices, are there any states in the United States where these devices are not used?

A. No. They are used throughout the United States.

Q. Are there any states that specifically accept Electrodermal Screening as a modality for a health care practitioner?

MR. ARMSTRONG: Objection.

JUDGE DeBUSSCHERE: Basis?

MR. ARMSTRONG: He has asked the witness are there any states that accept EDS as a modality. That's not relevant to this case. It's not relevant to the whole, it's not relevant, period.

[2851] JUDGE DeBUSSCHERE: It's relevant to the issue of Respondent's case, that his treatment is non-traditional treatment, and whether it's within the mainstream or without the mainstream, which has been an issue raised.

MR. ARMSTRONG: So whether a state accepts it makes it mainstream or not mainstream, is that what you said?

JUDGE DeBUSSCHERE: It's a factor in that consideration, so objection overruled.

Q. Are there any states that specifically sanction EDS, the use of these devices for EDS?

A. Yes, there are a number of states, specifically Florida and Massachusetts, allow the use of EDS or EAV, as it's also called by the German designation, or it's called German Electroacupuncture. They allow the use of the instrumentation under the acupuncture regulations.

Other states, particularly Arizona and Nevada, allow the instrumentation under homeopathic regulations.

Q. In those states they allow homeopathy, in other words?

A. Yes, they do.

Q. Now, in the United States, as we have [2852] learned so far, it's true, isn't it, that the FDA will not clear a device for Electrodermal Screening; is that correct?

A. That is correct.

Q. Has the FDA cleared devices other than yours, as galvanic skin response devices?

MR. ARMSTRONG: Objection, Your Honor.

MR. BISHIN: He's an expert in this field, Your Honor.

MR. ARMSTRONG: He just made the statement that the FDA has cleared, the FDA cleared EDS, and then he made an answer, and he said other than your device, has the FDA cleared. That's not been established.

MR. BISHIN: No, no, other than his device, has the FDA cleared galvanic skin response devices.

JUDGE DeBUSSCHERE: I'll allow that question, if that's the objection. Go ahead.

Q. Has the FDA cleared galvanic skin response devices, computerized galvanic skin response devices, that are used in the health care industry, other than clearing yours?

MR. ARMSTRONG: Objection, Your Honor.

JUDGE DeBUSSCHERE: Overruled. Can you [2853] answer that?

A. I'm not sure. Do you mean other EDS devices?

Q. Yes, manufactured by others, not you.

A. Yes, they have.

Q. About how many others have been cleared?

A. I know of three other companies.

MR. ARMSTRONG: All right. I renew my objection, Your Honor, to the whole line of questioning regarding the galvanic skin response devices. The objection is for vagueness.

JUDGE DeBUSSCHERE: Your objection is on the record, and so you have that, so you don't need to make, in regards in your objection to vagueness on galvanic skin response devices and EDS devices, your objection to vagueness is on the record. You have that.

It's part of the record. You don't need to make an objection every time the question is asked. Thank you. Next question.

Q. These are the devices. Are you familiar with what the FDA has cleared them for?

A. Yes, I am.

Q. And what has the FDA cleared those other devices for?

A. Some devices for biofeedback, and one device [2854] for patient data acquisition.

Q. Okay. Now these particular companies, however, they are devices used for Electrodermal Screening by practitioners, is that correct?

A. Yes.

Q. Now has the FDA ever taken any action against those companies that distribute, the ones that have the clearances that distribute these devices?

MR. ARMSTRONG: Objection, Your Honor. What the FDA has done with another company is not relevant to this hearing, because we're talking about the LISTEN device and his company. We can talk about crimes in other countries all day long. No relevance here. Waste of time.

JUDGE DeBUSSCHERE: There has been questions on direct with Mr. Ogden of what FDA action, whether or not they take action or not action –

MR. ARMSTRONG: Against this company.

JUDGE DeBUSSCHERE: – with regards to the process procedure and action, what the FDA has done, so it's relevant in that respect.

MR. ARMSTRONG: Since we're not talking about federal violations any more, it's still not [2855] relevant.

JUDGE DeBUSSCHERE: Your objection is overruled.

MR. BISHIN: Would you read back my question, please.

(The pending question was read.)

A. I have not heard of any.

Q. Now, would you expect to hear, if they had?

A. It's a small industry, yes.

Q. Now has the FDA ever taken any action against you for distributing these devices?

A. None.

Q. Have they ever sent you any regulatory letters telling you to cease and desist?

A. None.

Q. Have they ever brought any lawsuits against you?

A. No, they have not.

Q. Have they ever called you and said we don't think you should be doing this?

A. No.

Q. Do you have a history with the FDA?

A. Yes, I do.

Q. When did you first have contact with the FDA?

[2856] A. The first contact would have been about 1990, somewhere in the early 90s, when we were setting up an IRB with the LISTEN system, and even though we received information that it was a Non-Significant Risk device, we submitted information to the FDA all about the IRB, and about the actions of the IDE.

Q. Okay, and IDE means Investigational Device Exemption?

A. Yes.

Q. So your first contact with the FDA was in the 1990's, you said?

A. Yes.

Q. Have you had contacts with the FDA since the early 90s?

A. Yes. I have communicated with them during submissions that I have had. I have been to the FDA in their building in Rockville, Maryland, meeting

with department heads, and with other staff that they had.

Q. And about how much time would you say you have spent dealing with the FDA over the last, I guess it's 11 years, something like that?

A. Yes. In any given year it probably represents four months of my work.

[2857] Q. Let's go into, and what has been the subject of your contacts with the FDA?

A. The subject was because of submissions.

Q. What particular product?

A. With the LISTEN system and with the Digital Conductance Meter.

Q. And also the Orion?

A. With the –

MR. ARMSTRONG: Objection, leading the witness, suggesting the answer.

JUDGE DeBUSSCHERE: Objection sustained, leading the witness.

Q. Have you also had contact with the FDA regarding the Orion?

A. Yes, I have.

Q. Is that the extent of the subjects of your contacts with the FDA?

A. Yes.

Q. So is it fair to say that basically you have been in contact with the FDA regarding these kinds of products since 1992?

A. Yes.

Q. Let's talk about the beginning of your relationship with the FDA, FDCA in 1992, say that had to do with Investigational Device Exemption.

[2858] A. Yes.

Q. Let me ask you this before, let me, since you have mentioned that, call something to your attention here. I believe this is Respondent's Exhibit 4 on page ten. Would you take a look at Respondent's Exhibit 4, please.

A. Yes, I have looked at this.

Q. What is Respondent's Exhibit 4?

A. My company sent the FDA a letter in, as it states, February of '92, requesting advice information on the Investigation Device Exemption, particularly for whether the instrumentation was Non-Significant Risk or not.

Doctor Blackwell responded back that it was a Non-Significant Risk device.

Q. What's the significance of being a Non-Significant Risk device, why would you want to know that?

A. The IRB, the Institution Review Board and processor manufacturer come under the abbreviated regulations for conducting the research, instead of what are referred to as a formal study.

Q. What is the significance of that, for the Panel?

Q. Well, basically with a Non-Significant Risk [2859] device you don't even have to tell the FDA that you exist. Now we knew that beforehand, because the IRB that we had set up had already defined the instrument as a Non-Significant Risk, but we still wanted to contact the FDA and be able to see what their –

Q. My question has to do with what is the significance of abbreviated, whatever it was you said, abbreviated requirements described in Section 812.2 B of the IDE regulation, what is the significance of that?

A. The importance as a Non-Significant Risk device, it's considered it's not harm.

Q. Thank you. Let me ask you this: When you have a determination that it's a Non-Significant Risk, do you have to have the FDA actually approve your investigation and research?

A. No, you do not.

Q. Do you have to tell them anything about the research?

A. No, you do not.

Q. When does the FDA get involved, then when you have abbreviated requirements for an investigational device?

A. When you submit your PMA, your premarket approval information to the FDA.

[2860] Q. In other words, after you finish doing your research, and you're ready to ask for an approval?

A. That's correct.

Q. At some point – let me just go back. I neglected to ask you something general about these devices. You testified that the FDA does not clear these devices for Electrodermal Screening.

MR. ARMSTRONG: Objection.

MR. BISHIN: That's a preface to a question. It's already been testified to.

JUDGE DeBUSSCHERE: Overruled.

Q. Although the FDA does not clear them, what is the position of other countries with regard to these devices?

A. The instrumentation is accepted in many other countries.

Q. Is it accepted by government authorities for EDS use?

A. Yes.

Q. Can you give us some of the countries in which that's true?

MR. ARMSTRONG: Objection, Your Honor. Objection to this one, and I already objected to the last question. It's not relevant, not needed. There's a lot of products and devices accepted in [2861] Korea, not here, a lot of things accepted in other countries.

It's not relevant to determine if Doctor Ames treated Patient 1 with a LISTEN device, not even related to allergy treatment. This is getting way into a historical. Waste of time, not relevant, and won't help the Panel.

JUDGE DeBUSSCHERE: Mr. Bishin, do you want to respond?

MR. BISHIN: This is related to the reasonableness of the decision to use this device.

MR. ARMSTRONG: Because other countries accepted it?

JUDGE DeBUSSCHERE: It goes to the issue of non-traditional treatment, which is Respondent's under RCW 18.130.180(4). Objection overruled.

Q. Can you tell us the names of some of the countries that allow these devices to be marketed as EDS devices?

A. European countries, African countries, Australia.

Q. Can you tell us some of the European countries?

A. Germany, France, England, Spain, Italy, Greece.

* * * *

[2870] hear?

MS. PAXTON: Yes, that's-what I wanted to hear, Thank you.

Q. All right. Now Exhibit 1 is dated – you don't have it in front of you any more. This was sent on August 18th; is that right?

A. Yes.

Q. Now prior to this submission in August of 1992, did you make an earlier submission for a 510 K clearance in that year?

A. Yes, I did.

Q. Do you remember when you did that?

A. I did it in January of '92.

Q. And what was the, what was that for?

A. That was for the LISTEN system.

Q. And what happened to that particular submission?

A. The FDA responded with some questions. I responded back. Then the FDA rejected that submission because of acupuncture claims.

Q. Can you state a little bit more, a little bit more elaborately what the nature of their objection was?

A. Just the information on acupuncture, that they had basis points.

[2871] Q. What particular claims did they say that they wouldn't be able to clear?

A. Just the simple connection with acupuncture.

Q. Whether it could be used in some way for acupuncture; is that what you're saying?

A. Yes.

Q. Then after that clearance was rejected, why did you submit this clearance for the Digital Conductance Meter?

A. It was after that I had conversations with the FDA in the submission of the LISTEN 510 K. I asked what things could be done for submission, and they said I needed to exclude the acupuncture claims, and submit the instrumentation without the acupuncture claims.

Q. And is that why you submitted the DCM submission?

A. Yes.

Q. Do the people you submitted it to, were they the same people you had been talking about with the LISTEN?

A. Yes.

Q. Was your purpose in getting the DCM clearance, was that to, in effect, clear the LISTEN?

A. It was to clear the ohmmeter and the [2872] capability for the LISTEN system without the acupuncture claims.

Q. Was it to clear the LISTEN system?

A. Yes.

Q. Was it in order for you to be able to market the LISTEN system?

MR. ARMSTRONG: Objection. He asked the question and answered it.

MR. BISHIN: No, I changed it –

JUDGE DeBUSSCHERE: Overruled. It's not asked and answered. What was your question? Restate it.

Q. My question was did you seek the DCM clearance in order to be able to market the LISTEN device?

A. Yes, I did.

Q. And after you obtained the DCM clearance, did you market the LISTEN device?

A. Yes, I did.

Q. Were the people that you were dealing with at the FDA aware of this?

A. Yes.

Q. Had they ever complained about that?

A. No.

Q. Now, in making your submission to the FDA [2873] about the Digital Conductance Meter, that second 510 K submission, tell the Panel what it was that you actually submitted, what were the components of the device that you submitted to the FDA?

A. The components were the galvanic skin response, ohmmeter circuitry, the computer, the software and the signal generator.

Q. Okay, and the signal generator, was any question ever raised about that at all, by the FDA?

A. Yes.

Q. What question was raised?

A. The question was what were the signals, what did they look like. I had to get a specific oscilloscope to be able to print out all the square wave, sine wave and triangle wave for the FDA, and submit that as an addendum.

Q. Did they approve that?

A. Yes.

Q. So they accepted the DCM with the signal generator at this point; is that correct?

A. That's correct.

Q. Now what exactly does the signal generator do?

A. It sends out a signal just like music, but in this case it doesn't go to speaker, it just goes [2874] to a probe antenna device.

Q. You say it sends out a what again?

A. An electromagnetic field is what it generates.

Q. What kind of electromagnetic field does it generate?

A. A pulsing.

Q. And it's just one electromagnetic field? Tell the Panel how the signal gets generated.

A. The signal is based on a digital pattern, zeros and ones in this particular, zeros and ones, and when they come out they make different patterns, different electromagnetic fields.

Q. Are you saying the signal generator will generate different electromagnetic fields?

A. Depending what the operator does, yes.

Q. How many different electromagnetic fields can the signal generator generate?

A. It's a computer, so it can generate just about anything that somebody would request.

Q. What do you mean by just about anything?

A. Any kind of pattern, a variety of different patterns.

Q. There is more than one kind of electromagnetic field, is that what you're saying?

[2875] A. The electromagnetic field is the same. The pattern can be different, there are multiple different patterns.

Q. Patterns of what?

A. The patterns can simulate foods, they can simulate products, they can simulate a number of different things that are in the environment.

Q. Can you explain to the Panel a little bit about what you mean by simulating, for example, food?

A. The concept of the signal is it simulates things just like a homeopathic product, that it has the signal for the particular product.

Q. Now, this device can be used for Electrodermal Screening; isn't that correct?

A. Yes.

Q. Is it also used by NAET practitioners?

A. Yes, it is.

Q. Is it used in the same way it's used by EDS people?

A. No, there is a different protocol.

Q. Does the signal generated have a special role for NAET practitioners?

A. Yes, it does.

Q. What is that role, as you understand it?

A. It's to be able to output a signal to see if [2876] it will, in this case, provoke work with applied kinesiology.

Q. Now, I want to call your attention again to the clearance for the Digital Conductance Meter.

MR. TENNIS: Exhibit?

MR. BISHIN: I'm just trying to find it. It should be the 1996 document, Exhibit 2, page three.

I want you to read to the Panel the, and for the record –

MR. ARMSTRONG: Objection. The Panel can read for themselves.

MR. BISHIN: This is for the record.

JUDGE DeBUSSCHERE: Let's see.

MR. BISHIN: I'm going to ask a question about this, Your Honor.

JUDGE DeBUSSCHERE: Okay, objection overruled, but you can renew your objection if he tries to repeat it.

Okay, go ahead, Mr. Bishin.

Q. I'll read the bottom paragraph to you, because I want to ask you what this means.

"This letter will immediately allow you to begin marketing your device as described in 510 K premarket notification. An FDA finding of

* * * *

[2879] A. Yes.

Q. What is the concern, that the public might be misled by a clearance?

A. Yes. The documentation says so, and they have told me in person.

Q. So therefore any materials that you sent to Doctor Ames would not reference the clearance; is that correct?

A. That is correct.

Q. Now I want to talk to you a little bit about this particular device, and its various uses. Is there any danger, any physical danger in using this device?

A. No, there is not.

Q. And it does use electricity and it does emit these electromagnetic fields and patterns, as you have just indicated. That might sound to lay people

as if it would be dangerous. Can you tell us why it isn't?

A. When you do the submission to the FDA, the FDA has no specific electronic standards. You have to go to other groups, underwriter laboratories, electronics, electrical engineers, called the I triple E. You have to use circuitry chips that have been tested so that they have the isolation that you [2880] need.

The particular circuitry in this was developed over 10 years ago, I believe, and the chip that was available then is called an isolation amplifier chip, and it was submitted to the FDA. I had to submit the electronic literature, the underwriter laboratory, the I triple E standard that it fell under, and the FDA gave clearance for this instrumentation to touch the skin.

Q. Has anybody ever complained about being harmed by this device?

A. No.

Q. You never received a complaint from a customer?

A. No.

Q. Have you ever heard of customers of any other manufacturer of these types of devices, complaining that they were injured by this device?

A. No.

Q. Have you ever heard of any lawsuits for product liability being brought because of this device?

A. No.

Q. The signal generator, does it, how much energy or power does it emit when it's being used in [2881] the way you described earlier?

A. Less than the actual ohmmeter circuitry.

Q. And the ohmmeter circuitry is what?

A. It can be up to five volts and eight to 10 microwaves.

Q. And the FDA never raised any concern about the safety of this device; isn't that correct?

A. That's correct.

Q. That's why you have a Non-Significant Risk determination; is that correct?

A. That's correct.

Q. Now, just to give you a little about the history, you testified to submitting a device to the 510 K pre-market notification for the device under the name LISTEN, and you testify that it was rejected, and then you went to the DCM, it was accepted, so you started marketing the LISTEN.

You're not marketing the LISTEN any more; isn't that correct?

A. That's correct.

Q. You're marketing these devices that you mentioned to us before. Tell us a little bit more, fill in

the picture of what happened there, why did you stop marketing the LISTEN device?

A. In 1997 a corporation came in and requested

* * * *

[2883] Q. Now, drawing your attention to the device that you identified before, the one to your left, which you have called the LISTEN, have you ever been contacted by the Washington State Department of Health, or any representative of the Washington State Department of Health, with respect to that device?

A. No, I have not.

Q. So they have never inquired, tried to find out any information from you about that device; is that correct?

A. That's correct.

Q. Okay. Now were you ever contacted by anybody from the office of the Attorney General in the State of Washington with respect to that device which I'm referring to, the LISTEN device to your left?

A. No.

Q. Has anybody from any governmental agency or any employee of the State of Washington, as far as you know, ever attempted to find out anything from you about how this device functions?

A. No.

Q. Has anybody from the State of Washington, employed by the State of Washington, as far as you know, ever attempted to find out if this device poses [2884] a risk to anyone?

A. I don't know.

Q. So you don't know whether they have or not?

A. I don't know whether they have or not.

Q. I'm asking if they have contacted you.

A. No, they have not contacted me.

Q. Have you ever had a report that anybody at your company was contacted by anybody from the State of Washington with respect to this device?

A. No.

MR. BISHIN: I'm going to rest at this particular time with this witness.

JUDGE DeBUSSCHERE: Let's go off the record for one minute.

(Discussion off the record.

JUDGE DeBUSSCHERE: Back on the record. Mr. Armstrong, cross-examination?

MR. ARMSTRONG: Yes.

JUDGE DeBUSSCHERE: Do any of the Panel members need a break? We'll just go off the record for one minute.

(Discussion off the record.)

JUDGE DeBUSSCHERE: Okay, we're back on the record. Mr. Armstrong, cross-examination?

MR. ARMSTRONG: Yes.

* * * *

[2891] A. They weren't different, no.

MR. BISHIN: Objection.

Q. Well, I asked did you submit the exact same thing, and you said no?

MR. BISHIN: Object to the vagueness of it. You included labeling in there, and included some other things.

MR. ARMSTRONG: Well, there's a lot that goes in 510 –

JUDGE DeBUSSCHERE: Objection overruled. The question has been answered. Your next question.

Q. You answered it, correct?

JUDGE DeBUSSCHERE: No, he answered did you exhibit the exact same thing. He said no. Next question.

Q. For the DCM submission in August you submitted it, what was the labeling claim for that submission?

A. Biofeedback.

Q. Was it submitted for anything else, as in allergy treatment?

A. No.

Q. Allergy diagnosis?

A. No.

Q. Curing of any ailments?

[2892] A. No.

Q. Can the device that you submitted in August 1992, the DCM, can it be used to diagnose allergies, food allergies, used to diagnose food allergies?

MR. BISHIN: I'll object to the question's vagueness. Used by whom, and what does the word "can" refer to? Is he asking him a question about whether or not it has the capability of performing a health care function.

It's a little bit, depending on what the meaning of the question is, it may be calling for an answer from him that he can't give, because he is not a health care provider.

On the other hand it's a –

MR. ARMSTRONG: That's a good point.

JUDGE DeBUSSCHERE: I'll sustain the objection. Just restate your question, Mr. Armstrong.

Q. Mr. Clark, can the DCM which you submitted in August 1996, is it capable of presenting a medical diagnosis for food allergies?

A. No.

Q. Are you a medical doctor?

A. No.

Q. Are you able to tell us what a medical [2893] doctor could tell us regarding a medical diagnosis, are you able to provide a medical diagnosis to the Panel here today?

A. Am I?

Q. Yes.

A. No.

Q. The LISTEN device that was submitted in January 1992, does that machine have the capabilities of providing a medical diagnosis for allergies?

A. No.

Q. How about curing allergies?

A. No.

Q. Does the LISTEN device or the DCM, which you submitted both of them, and so you know the capabilities of both, do they have the capabilities of providing acupressure to human skin, can those devices perform acupressure on the human skin?

A. Acupressure, as a mechanical –

Q. Yes.

A. No.

Q. So they can't provide acupressure?

A. That's correct.

Q. The LISTEN device that was rejected in 1992 because whatever requirements were not met, did you change any of the functions or capabilities, and [2894] re-submit it in August?

A. No.

Q. Or did you have another whole different product that you re-submitted in August?

MR. BISHIN: He answered the question. He said no.

MR. ARMSTRONG: I asked a different question, and I don't have the answer yet.

JUDGE DeBUSSCHERE: Okay, that question stands. You didn't get a chance to complete your second question. Complete your next question, and then you can object if you wish, Mr. Bishin.

Q. In August 1992 did you submit a new or different or modified device for submission for your 510 K, new or modified?

A. The acupuncture claims were removed. That's the difference.

Q. So you just changed the claims?

A. That's correct.

Q. There were no specification differences?

A. That's right.

Q. No software differences?

A. That's correct.

Q. No electronic differences?

A. That's correct.

[2895] Q. The voltage that it output was the exact same?

A. Yes.

Q. So you just took the same device, took off the claims, and it was approved, and it was approved for what?

A. It was cleared.

MR. BISHIN: Objection. Asked and answered.

JUDGE DeBUSSCHERE: Overruled, You can answer it. Restate the question.

Q. What was the DCM that was submitted in August 1992, what was it cleared for?

JUDGE DeBUSSCHERE: That was asked and answered.

MR. BISHIN: That's why I objected.

MR. ARMSTRONG: That's why you objected.

Do you own the patent for the LISTEN device?

A. No.

Q. Who has the patent for the LISTEN device?

A. Nobody has the patent.

Q. It's not patented?

A. No.

Q. How about the DCM?

[2896] A. No.

Q. There's no patent for the DCM?

A. No.

Q. How about the new products, the Orion?

A. There are applications for the Orion that I received a patent for in the year 2000, for outputting signals for treatment with additional hardware, including lasers, infrared and other modalities.

Q. Would that make it a different product than is sitting right here?

A. Yes.

Q. So you have received a patent for a device that's not sitting in this room?

A. Yes.

Q. This device that's sitting in this room, which we're calling the LISTEN, is not patented?

A. Yes.

Q. When the FDA cleared the DCM device, did they clear it for EDS, Electrodermal Screening?

A. No.

Q. So it's not cleared for Electrodermal Screening?

A. No.

Q. Even though in use, it has the capability of [2897] Electrodermal Screening, it's not cleared for that?

A. Yes.

Q. Does that mean that practitioners that you sell the device to, that they can use it for Electrodermal Screening?

MR. BISHIN: Objection. Question of law about off-label use.

Q. I'm asking your understanding.

JUDGE DeBUSSCHERE: I ruled that it's a question of law of whether or not, but he's asking here in particular what his understanding is. You can answer the question.

MR. ARMSTRONG: Your Honor, I withdraw the question because it's dealing with a legal

conclusion. I don't want Mr. Bishin to be able to ask about off-label use either. If you're going to allow me to, I'll be glad to allow him to, but I don't want him to answer the question because –

JUDGE DeBUSSCHERE: I said I ruled that the question about what is off-label use is a question of law, but that you can ask this individual about his understanding.

MR. ARMSTRONG: I'll withdraw the question, motion to strike my own question.

JUDGE DeBUSSCHERE: Your statement, you

* * * *

[2922] A. Yes.

Q. Now, you said there are other people selling similar things.

A. Yes.

Q. If I buy one in Germany, is the signal coming out going to be the same for egg?

A. I don't know. So many of the instruments that are out, they're ones that have taken my software. They actually took my LISTEN and incorporated on their system, so those I'm aware of.

Q. How do you learn this, I mean where did you learn that you could transmit egg with a signal, fish with a signal, and how did you decide what the

signals would be, I mean what's the theory or whatever behind it?

A. The theory is I actually had to wait for the full definitions, NIH, and through the patent office, and the patent office stated that by them simulating a homeopathic, and therefore I am putting in a signal that represents egg, for example, and that particular signal simulates having the egg there.

I can go through that process. It's a lot shorter than 10 minutes, but I can give you that.

Q. Well, that's okay. I don't need the process. Probably I don't understand the process [2923] anyway.

What I'm trying to say is there a logic, science, something that's accepted by more than one person, you; is there a dictionary, I mean can somebody else make one like that?

A. Yes, there are other people that if they knew what I knew, the National Institute of Health, Office of Alternative Medicine issued a Panel report in 1993. This was 14 years after I developed it, and they presented in there that non-ionizing, non-thermal, frequency specific electromagnetic fields, can produce a beneficial or a harmful affect.

Q. I understand that. I have done a course in homeopathy myself.

Forgive me, I think I have to be excused for a minute here. I have a pager I have to answer.

JUDGE DeBUSSCHERE: Let's take a five-minute recess, and depending on when you're ready. We'll go off the record.

(A break was taken.)

JUDGE DeBUSSCHERE: We're back on the record. Mr. Clark is testifying.

Doctor Uberoi you were asking questions. Go ahead.

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[3019] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

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| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | ) | Docket No. 02-06-A-1012MD DAY 5 |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:

ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:

WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:

KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.,
Public Member

Renton, Washington
February 10, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[3026] everything that covers that matter, so it's now an opportunity for the Respondent to continue the presentation of his case.

Your next witness, Mr. Bishin?

MR. BISHIN: My next witness is Doctor Ames. Doctor Ames, will you please take the stand.

JUDGE DeBUSSCHERE: Doctor Ames, I know that you were sworn in at the last time we had the hearing in this case, but I would again ask that you be sworn in for today's hearing. Would the court reporter swear this witness in.

GEOFFREY S. AMES, M.D.,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

*BY MR. BISHIN*:

Q. Doctor Ames, where were you born?

A. I was born in Methodist Hospital in Dallas, Texas.

Q. How long did you live in Dallas, Texas?

A. Eight years.

Q. Where did you go from there?

A. Richfield, Connecticut.

Q. How long did you live there?

A. Until my junior year in high school, age 17.

* * * *

[3036] allergy.

I was amazed. She was also amazed that a simple treatment could cure my weed allergy, where

she also tried immunotherapy for years, and it did not work on her.

Q. Why were you amazed at the cure for weed allergy?

A. Because the standard practice for treating food allergies is just avoidance. It's very hard to cure a food allergy, so most allergists will just say avoid that food.

Allergy shots or sublingual allergy drops have limited success in treating food allergies.

Q. Okay, so that particular sort of a chance encounter, you're saying about NAET, how did that lead you to get further acquainted with the NAET therapy?

A. Well, I did call her office and I looked at her web site to learn more about it.

Q. Who is this?

A. Sorry, Doctor Nambudripad.

Q. All right, so did this person you met at Doctor Rea's center tell you about Doctor Nambudripad?

A. Yes. She gave me the web address.

[3037] Q. So the next thing you did was to go on the Internet and check out the web site; is that it?

A. Yes. Subsequently I took more courses from the American Academy of Environmental Medicine

and the American Academy of Otolaryngic Allergies, and I also met fellow colleagues who had already previously taken NAET Courses.

Q. How did you know that they had taken these courses?

A. I asked them. I said have you ever heard of NAET, and they said, Sure, I have already taken basic and advanced courses. I asked them how does it work, and they said it works fantastic. You must go down there and try it out yourself.

Q. Now, who were these people, these were people who were attending the same courses in allergy medicine, is that what you're saying?

A. Yes. One is Doctor Brownstein, Doctor David Brownstein, an author there in Michigan.

Q. Were they doctors, these people?

A. Medical doctors.

Q. How many doctors would you say you spoke to?

A. Around 20 doctors.

Q. So you talked to about 20 doctors at these various courses about NAET?

[3038] A. Yes.

Q. Okay, and of these 20 that you spoke to, did they all practice it?

A. They all practiced it.

Q. These are medical doctors?

A. These are medical doctors.

Q. So having spoken to them about it, what generally did they tell you besides the fact that they thought it was fantastic; what was fantastic about it?

A. Well, they said it's very quick. Patients don't have to come back for years, and spend lots of money in getting treated. It's very safe. Nobody has ever died from it, it's harmless, there's no side effects, and they said they get fantastic results.

They might not be able to cure everybody of allergies, but it's the best therapy they have ever encountered.

Q. You say "nobody has ever died of it." Why would they mention that?

A. Because just doing a prick test, an intradermal skin test testing for allergies can be dangerous. Say a person is very allergic to peanut allergy, they can actually die from testing, or they could have a severe reaction from immunotherapy. If

* * * *

[3042] First of all, did she lecture during the 16 hours?

A. She lectured pretty much the whole time.

Q. Was it really a full 16 hours?

A. Yes.

Q. How much lecturing did she do?

A. She lectured the whole time, except when giving demonstrations and during breaks.

Q. Can you describe her, how she appeared to you, and what your evaluation was of her in the presentation?

MR. ARMSTRONG: Objection, Your Honor, relevance.

MR. BISHIN: I can't hear you, Counsel.

MR. ARMSTRONG: Objection, relevance.

JUDGE DeBUSSCHERE: Overruled.

A. First of all she has a Ph.D. in Oriental medicine. She's a doctor of chiropractic and a trained kinesiologist.

She's very enthusiastic about her approach, because she, herself was allergic to every food in the world except rice and broccoli. For three years all she ate was rice and broccoli.

She had to wear the same blouse every day for three years. She would wash her blouse out each

* * * *

[3044] she was saying?

A. She had told us that she had already cured herself of her allergies, and that she had already

treated thousands of people, and cured them of their allergies.

She had a symposium once a year for people that have taken the courses to come back and give their case histories.

Q. Did any of the physicians or health care practitioners of this course or other courses you went to, ever verify or support what she was asserting?

A. Yes, definitely.

Q. That's what they were referring to when they talked about fantastic results?

A. (Nods head.)

Q. Is that correct?

A. Yes.

Q. You have to answer the question verbally.

So you went to these courses, and you said you were still skeptical at that particular time. Did you decide to pursue an interest in NAET at that time?

A. Yes, I did. I decided I would choose five of my worst allergic patients, and give them free

* * * *

[3051] kinesiology, but it was all new to me. I had never had any kinesiology courses before, and I was still skeptical.

Q. Now, have you found any evidence that supports the idea that this works?

A. Well, I have literally two of the strongest people in the entire world as my patients. They're the world power lifters in their age categories. They actually hold world records.

I can tell them to use all their might, and put an allergen in their hand, and their arm will go totally weak. I also did this with a Kennewick police officer in his 20's. He could definitely out power me, and –

Q. What was his dimensions?

A. He was around 220 solid muscle, and I found out he was allergic to eggs. It made his arms totally weak with just one finger.

Q. What do you mean by one finger?

A. I just used my index finger to pull his arm down. He couldn't hold his arm up.

Q. When did that happen, when did these experiences occur?

A. Well, they happened in the past by at least two power lifters. I actually saw them in December.

[3052] Q. Now, at the beginning you weren't seeing these power lifters when you initially encountered NAET, were you?

A. No.

Q. What was the evidence at the time you started to take this seriously?

A. Well, empirical evidence. I would do it on my patients. I'm not trying to hurt their arm. I only use about 10 pounds of pressure. I'm not trying to overpower the patient, or the patient is not trying to overpower me. Every time I put the allergen in their hands, their arms would go weak, and I would correlate that with blood testing.

When the blood test was positive, at the same time the arm would go weak, when I test them for that allergen. I had a very good correlation of blood testing.

Q. Tell us how you did that, to assure that you weren't in some way affecting your little test of its effectiveness?

A. Well, I always try to do blood testing first, unless patients can't afford it. Let's say somebody has a very strong reactivity to a food, then I'll test different things that they might not be allergic to, for instance, calcium or salt or vitamin

* * * *

[3066] moment.

Can I show this to the witness, Your Honor?

JUDGE DeBUSSCHERE: Yes.

Q. Showing the witness Exhibit 5. I believe it's Exhibit 5. Yes, Respondent's Exhibit 5.

Will you take a look at that, please?

A. Yes.

Q. Does that refresh your recollection about when you took the UCLA course?

A. Yes.

Q. So about when was that?

A. November '97 to May '98.

Q. Had you bought the device by that time?

A. Yes.

Q. You had bought it by then?

A. Yes.

Q. So it was somewhere between the NAET course and this course that you bought the machine?

A. Yes.

Q. When did you have these conversations with Mr. Clark, how many months before you bought the LISTEN device?

A. Approximately three to four months. I would call him up about once a month and talk to James Clark or his brother Bill Clark, and ask questions [3067] about these machines.

Q. Would that have been after or during or before the first NAET course?

A. That would be after the first NAET course.

Q. Okay. Why did you take the UCLA acupuncture course, having had the NAET course, why did you feel you needed that course?

A. Well, prior to medical school I had the opportunity to learn acupuncture as a non-practitioner in Marin County, California, and that got me interested in going to medical school, so acupuncture has always been of interest to me.

I understood that, according to acupuncture theory, that diseases could be caused by a blockage of energy in a meridian, and an acupuncturist, over time, could cure allergies with acupuncture.

I also had patients who were addicted to cigarettes, nicotine, and some pain patients, and I wanted to use acupuncture on these patients.

Q. Why didn't you think that the NAET would take care of that?

A. The NAET can be used to treat smoking addiction, but acupuncture is also another good therapy for that. Sometimes one therapy might not work on a patient, so I wanted to further learn more

* * * *

[3076] because some people are not familiar with acupuncture. I don't give them a thorough course on acupuncture theory. I wouldn't have time to see patients if I did that. That might take me an hour.

Q. Okay, but you do tell them something about it?

A. Yes.

Q. What do you tell them, to the best of your recollection; do you have a standard little routine?

A. Oh, yes. I tell them that the theory is that the allergen held in their hand, if you're allergic to it, will close down the acupuncture meridians. The meridians go, the organs and the muscles.

Doctor Goodheart discovered that in 1964 that muscle will become weakened when exposed to an allergen, so then I describe the process that I'll be doing on them, the kinesiology test, which arm I'll be using, et cetera, and then I tell them that I'll be giving you simple acupressure along the back, and that you must stay away from the allergen for 24 hours if there is going to be a cure.

Q. Is that all part of the NAET protocol?

A. Yes.

Q. It is?

[3077] A. Yes.

Q. Now let's turn if we can – let me ask you this: Do you tell these people that this is not a conventional form of therapy?

A. Yes, I tell everybody that.

Q. What words do you generally use?

A. I say this is not a conventional form of therapy, it's a form of acupuncture, but we're not using needles, we're using acupressure.

Q. Do you ever use anything like a written statement of Informed Consent for this?

A. Every patient signs an Informed Consent before getting the first treatment.

Q. What generally does the Informed Consent say?

A. The Informed Consent basically says that, what NAET is, what it does, and basically that it has no side effects.

Q. Does it tell them that it's not conventional?

A. I have to look at it to refresh my memory.

Q. What's the point of it if you're not going to tell them it's not conventional?

A. What's the point of the Informed Consent?

Q. Yes.

* * * *

[3090] as Exhibit Number 8.

MR. BISHIN: Could the presiding officer show it to the Panel so they have a chance to look at it. It's not very long.

JUDGE DeBUSSCHERE: I'll have the Panel members look at Exhibit Number 8.

(Pause in proceedings.)

JUDGE DeBUSSCHERE: Exhibit Number 8 has been reviewed by the Panel members, and now Doctor Ames has it before him.

Your next question, Mr. Bishin.

Q. Doctor Ames, tell us when you ask patients to look at this and sign this form that's been marked as Exhibit 8?

A. Right before they get NAET treatments.

Q. Right before they get it?

A. That's right.

Q. Did Patient 1 sign this document?

A. No.

Q. Why didn't he sign it?

A. Because I never treated Patient 1 with NAET.

Q. So you never offered it to him?

A. I offered that he could –

Q. You never offered Exhibit 1 to him?

A. No, I never offered Exhibit 1 to the [3091] patient.

Q. Can you tell us when you – let me ask you this. Have you reviewed your entire chart and file for Patient 1?

A. Yes.

Q. Did you find a signed copy of that Informed Consent form in that file?

A. No.

Q. If you had treated him, would you have expected to find it in that file?

A. Yes.

Q. What is your practice with regard to that?

A. When people come in for chronic fatigue, it takes me so long on the second visit, that I have people get the NAET on the third visit, if they decide to go with NAET.

On the second visit I thoroughly demonstrate NAET to the patient, so they know what they're getting into.

Q. So my question is when would you normally have them sign it?

A. On the third visit.

Q. On the third visit, and this was only the second visit; is that what you're saying?

A. Correct.

[3092] Q. Now, is this a routine of yours, is this a routine that you follow generally, strictly, loosely, what?

A. I follow this routine strictly.

Q. That's sort of your protocol?

A. Yes.

Q. Was that your protocol at the time that you saw Patient 1?

A. Yes.

Q. Now let's go to that second visit, if you would. Could you describe for us what happened at that visit, to the best of your recollection, what you did?

A. The second visit I described what was abnormal in his laboratory values, and how to correct these. I also described to him that he may have food allergies because the RAST test showed positive to different foods, so I said that you could do an avoidance of these foods to see if you feel better, give yourself a re-challenge, since these are not life-threatening food allergies, they're igG food allergies or delayed allergies.

Q. Let me interrupt you. I want to lay a foundation as to just exactly what was going on during this meeting.

[3093] At this particular visit did you have reports from the laboratory about Patient 1?

A. Yes.

Q. And did you bring those to the attention of Patient 1?

A. Yes, the patients –

Q. Yes or no.

A. Yes.

Q. Did you discuss the findings of the laboratory?

A. Yes.

Q. All right. Did you go over each finding?

A. Yes.

Q. You did, all right. Now much time would you say you took to go over the findings from the laboratory?

A. It takes most of the visit.

Q. About how much time would it take?

A. About at least a half hour, up to 30 to 40 minutes.

Q. When you talk about discussing the results, what does that consist of?

A. Explaining, first of all, to the patient what these labs mean, because they have never seen these values, and they don't understand what the labs [3094] mean.

Then explaining what diseases are caused, or can be caused by these abnormal labs.

Q. You mean what disease these may be a sign of?

A. Yes.

Q. Okay, and what else would you be telling them?

A. I would be telling them that we have different ways to correct these. In the future you can do repeated lab tests, and see if they change, and if they do change, your fatigue will probably get better, since these abnormal labs can oftentimes be associated with fatigue.

Q. Now, this review of the lab results is that what you would have started with at this visit?

A. Yes.

Q. And after you had finished doing that review, would you have done anything else?

A. Yes, I thoroughly described the NAET technique. I demonstrated the technique to the patient, like I do with my other patients, so they know what they're getting into, so I don't have to do this on the third visit.

Q. So you say you demonstrated it?

* * * *

[3100] A. Yes.

Q. Why would you have done that?

A. Because when I'm demonstrating it, I don't like to get patient's oil from their hands on the probe, so I put paper around it.

Q. I think you testified on cross-examination several days ago, I guess last month, that you always lave the patients take off their jewelry; is that correct?

A. Yes.

Q. And did you have Patient 1 take off his jewelry?

A. No.

Q. Why not?

A. Because he wasn't being treated.

Q. Now Patient 1 told you that – let's see. He testified that you had told him that you didn't need the device any more because, or you hardly needed the device any more because you could now do that it does by telepathy; do you recall that testimony?

A. I recall that testimony, yes.

Q. Okay. Now did you say that to him?

A. No, I never said that.

Q. Did you say anything to him that had any of [3101] the elements of that statement, or that might suggest that to a reasonable person?

A. Well, the only thing I can think of is I tell some people that we can test for psychological allergies or subconscious allergies by saying the word, and sometimes that will provoke a weakness, sometimes that will not provoke a weakness.

Q. Now, it is true that you have testified already that you can do this testing without using the device, right?

A. Of course, yes.

Q. So you don't need the device to do the testing; is that correct?

A. No.

Q. Is it possible you told him that?

A. Yes. I tell almost every patient that I tell them they can bring in real foods or their dog hair or their house dust in a baggy, or their dirt around their house, so I tell all patients that, most patients.

Q. Okay, so to the extent that he thought you were saying that you could do it without the device, that would be true?

A. Yes.

Q. That part of it would be true?

[3102] A. Yes.

Q. Do you think you have any telepathic powers to emit these frequencies?

A. No. Otherwise I'd be able to understand my wife a lot better. I don't have any telepathic powers.

Q. Okay. Let's talk a little about, have you had a chance to review Patient 1's records?

A. Yes.

Q. Is your review sufficient, taken with your memory of it, to have an opinion as to whether he would be likely to have memory problems?

A. Yes.

MR. ARMSTRONG: Objection, Your Honor.

JUDGE DeBUSSCHERE: Basis of the objection?

MR. ARMSTRONG: The basis of the question is whether his memory and the records gives him sufficient to have an opinion on his memory problems.

JUDGE DeBUSSCHERE: What's your objection?

MR. ARMSTRONG: No foundation to establish that the doctor has said anything about memory problems. Now Counsel has mentioned memory

* * * *

[3113] The allergies were also causing muscle pain and fatigue.

Q. How did all this affect her life at that point; what was she reporting?

A. Well, it made it real miserable. For someone who has never had allergies, it's hard for them to understand how miserable one can be. She was in muscle pain, she had fatigue and it was just real hard for her to function, sometimes cloudy thoughts from the allergens, and always having to blow her nose.

Q. You say she had muscle pain. Did she have it throughout the day, part of the day, for a few minutes?

A. She would have it every day. It would vary in intensity. Sometimes it might only be a two out of 10, where 10 is the worst pain, or sometimes it might be five or seven out of 10, but every day she would have some muscle pain.

Q. Which particular muscles are we talking about?

A. Most of the muscles in the body.

Q. Most of the muscles?

A. Most of the muscles, that's right. Most of the trigger points typically found in allergy

* * * *

[3116] A. Yes.

Q. Now, how would you describe the difference between Patient 3 at the present time, and her

condition when she came to see you about the allergies?

A. She was a happier person. She has more energy, less nasal stuffiness, less generalized muscle pain. She feels the NAET has done this for her.

Q. Now, you didn't use the device to test her, though; is that correct?

A. I have used the device to test Patient 3, but I usually have her bring in samples from around her property and environment, little bags. We test new pollens that are arriving in the spring, and so forth.

Q. All right, let the ask you this: As the presiding officer indicated, the number of patients we were able to call was limited by the presiding officer. If you had been able to call all the patients who have done well with your therapy, how many would you have called?

A. I would have called hundreds, at least hundreds. I have treated at least hundreds of patients many times with NAET, with great success.

* * * *

[3119] A. Utah.

Q. After you received it, did it ever leave your office?

A. Yes. I brought it home once, and just kept it there while I was studying how to use it, since I'd rather study there than at my office.

Q. You never gave it to anybody?

A. No.

Q. You never sold it to anybody, did you?

A. No.

Q. You already testified you never charged for its use?

A. No, I never charged ever for the use of this machine.

Q. And you indicated before that when you do the NAET, sometimes you use it and sometimes you don't; is that correct?

A. That's right.

Q. When you don't use it do you charge less than you do when you do use it?

A. No.

Q. You charge exactly the same price?

A. Exactly the same price.

Q Have you ever had any problems with the device?

[3120] A. No.

Q. Did it ever cause anybody to have a shock, or anything of that sort?

A. No.

Q. Has it ever occurred to you that it might pose some kind of a danger to a patient?

A. No.

Q. Why not?

A. I talked to Jim Clark. He said that he was working with the FDA, and has been working with the FDA, and his machine is legal to sell to practitioners, doctors.

I can't feel any current going through this machine, and none of my patients have ever felt anything.

Q. Just give me a moment. I'm pretty close to the end here. Oh, let's talk a little bit about ham. You recall that Patient 3 said that you apparently tested her by just saying the word ham; is that correct?

A. That's correct.

Q. Would you describe that event to the Panel so we can get that issue fully covered.

A. Sure. I said the word ham, and I did a kinesiology technique, and her arms went weak. In [3121] the advanced course in NAET we –

Q. Just a moment, before you get into that. Why did you say the word ham?

A. Because I wanted to see if she had a subconscious or psychological allergy to ham.

Q. Why did you think of the word ham?

A. Because she had eaten ham the prior night, as well as a few other foods, and she had an allergic reaction, she thought she was allergic to something she had eaten the night before.

Q. So she actually came to you with that suspicion?

A. Yes.

Q. All right, and what was the reaction; do you recall, to the ham?

A. She tested physically allergic and psychologically allergic to ham.

Q. What was her actual reaction that brought her into your office?

A. I can't recall the exact symptoms that she had.

Q. Okay. so in any event, you took a history; is that correct?

A. Yes.

Q. You asked her what she had eaten?

[3122] A. Yes.

Q. She reported that one of the things she had eaten was ham; is that correct?

A. Yes, that is correct.

Q. So why did you test her with the word ham?

A. Because when I took the advanced course Doctor Nambudripad told us that sometimes people have a psychological allergy to a food, and you can say the food out loud, and the arm will go weak. Since it only takes me a split second to say ham, I might as well test for it, and her arm did go weak.

Q. Why did you say ham rather than use the device?

A. I did use the device, and she tested positive for ham on the device.

Q. Was that after you said ham?

A. No. I tested her for the physical allergy to ham first using the device. Then I tested her for the psychological or subconscious allergy saying the word ham after using the device.

Q. Now you can continue your answer about why you did this.

A. Well, to be real thorough. Some people can have a subconscious allergy to something, say for instance Patient 3 ate ham when she was a little [3123] child and threw up, or had some kind of allergic reaction, or maybe it wasn't even ham, but she associated ham with some other food, and she felt sick afterwards, so she may have been yelled at by her father while she was eating ham. Sometimes that can get imprinted on the mind as an emotional allergy or a subconscious allergy, so when one says the word, you can evoke a weakness.

Q. Are you telling us something that you were told by Doctor Nambudripad?

A. This is what we were told and taught in her advanced course.

Q. Did she have any evidence to support this?

A. She had empirical evidence. She doesn't have the double blind studies, or anything like that.

Q. Did she do any demonstrations that supported this?

A. Yes.

Q. She did?

A. Yes.

Q. Do you recall any of them?

A. I can't recall the exact foods, but she did demonstrate in class.

Q. Is there any scientific evidence that saying a word can have that kind of psychological affect on [3124] people?

A. Yes, of course there is.

Q. How?

A. There's lie detectors. When, say a child was molested as a youth, you can say the word molestation, or name the person that molested the child, and get a response on the lie detector, which is

actually a galvanic skin response machine, and that will actually influence the acupuncture meridians.

Q. Did you treat Patient 3 for the ham?

A. Yes.

Q. Did she ever report that same reaction again?

A. No.

Q. Did she eat ham after that?

A. Yes.

Q. She did, okay. Just for the record would you tell us a couple of the more dramatic results that you have gotten from your therapy with life-threatening allergies.

A. I had a man that had a life-threatening allergy to fish, all fish, and he was real frustrated, because he used to fish with his son all the time, and he couldn't even take the fish off the

* * * *

[3137] did not know anything about FDA law, clearance or approved or registered, anything like that.

Q. Didn't you say earlier today in your testimony that you wouldn't have a machine in your office if it wasn't FDA-approved?

A. I wouldn't have a machine in my office, I believe, that wasn't FDA-cleared, I said.

Q. Cleared could be what you said. What's the difference between registered and cleared?

A. I don't know the definition of this, I'm sorry. These are legal terms. I'm not an expert on this.

Q. What did you mean when you said FDA-registered; in your mind, what was your understanding?

A. Jim Clark had told me that the machine is approved to sell to doctors, and he has never had any complaints from the FDA, and he was allowed to sell this machine to doctors. That's what I meant by that, when I wrote this letter.

Q. And you believed it?

A. I believed Jim Clark, yes.

Q. Do you rely on most of the statements, how about everything; Mr. Clark has been open and honest with you about his machine, correct?

[3138] A. Yes.

Q. And you rely on the information that he gives you, correct?

A. Yes.

Q. You also testified earlier you consulted him, after you got the machine, you consulted him often, to try to find out questions about the machine, right?

A. No, that was before I bought the machine.

Q. Oh, before you bought the machine.

A. I consulted with him.

Q. After the machine you didn't call him up and ask questions, periodically?

A. No. I sent my nurse to one of his courses to learn how to use the machine. I didn't have any complaints about the machine. I had no reason to call him.

Q. Well, maybe I misunderstood. I thought earlier you testified that you called him maybe once a month, called him up constantly and –

A. You did misunderstand me, you didn't hear me. I said I called him before I purchased the machine once a month.

Q. About how many times did you call him, if you can remember?

[3139] A. Around three times.

Q. About three times, all about the machine and its operation, or some other purpose?

A. Well, I wanted to find out his dealing with the FDA, I wanted to see how well the machine works, how other people were satisfied, and different questions like that.

Q. Now, as far as investigating, do you have devices in your office, you have already testified that you do a thorough research and protocol to increase

the safety of your patients when you're doing treatments.

How about the devices that you use, medical devices, electronic devices, what type of thorough examination do you conduct to ensure that those devices are safe for your patients?

A. Well, basically I don't use many devices. I use vials and needles. I have an auto-plate machine, and I don't really use, I have a tongue depressor. I don't really use any big devices.

Q. What about the device that you had last time. It was a hand-held device, and looks like some tongs?

A. Right.

Q. What about that machine?

* * * *

[3155] later, so that clarifies that. Thank you,

When this all started and the Department started to question you after Patient 1 had put in the Complaint regarding the LISTEN device, why did you just not quit using it, the whole thing?

A. Why didn't I quit using the LISTEN device?

Q. Why didn't you quit, and say I won't use it?

MR. BISHIN: I have to object to this. This goes to what the Department told him, what letters were sent to the Department, what he responded to

it. The question assumes that there was a focus in the Department's investigation on the machine.

I can understand why Miss Paxton would have thought that was the case, but it's an assumption.

MS. PAXTON: But we're talking about the LISTEN device.

MR. BISHIN: We're talking about it now, but that's not what he was led to believe they were most concerned about when the investigation started. That's the problem.

You're going back to the history of this whole thing, and you're assuming what was going on during the time of the, well, I guess you're talking

* * * *

[3156] about when the investigation was going on, that's correct, isn't it?

MR. ARMSTRONG: May I respond?

MR. BISHIN: You're assuming what was said in that investigation.

JUDGE DeBUSSCHERE: Objection noted. Mr. Armstrong, your response?

MR. ARMSTRONG: I don't have a clue what Mr. Bishin is talking about, but my objection is he's mischaracterizing what the Panel member is assuming. That's improper. He has no clue.

JUDGE DeBUSSCHERE: I'll overrule the objection, and you can ask the question.

Do you remember what the question was, Doctor Ames?

THE WITNESS: No.

Q. (By Ms. Paxton) In the beginning, when you were made aware there was a problem, or at least someone thought in the Department there was a problem, because you were using the LISTEN device as part of the problem, why didn't you say okay, I'm going to quit using the device?

A. In the very beginning I wasn't aware that I had a problem using the device, from the statement of charges. Once I know the statement of charges, I knew [3157] that the LISTEN machine doesn't harm anybody, it doesn't hurt anybody, it's perfectly safe. It facilitates my practice.

If I use vials I might only be able to test 50 percent of the allergies. If I use the machine I can test more allergens and help that patient more, screen more allergens using the machine, so it really saves my practice time.

Q. Okay. When you got the LISTEN device, and you testified that it came with an operating manual, but basically nothing else?

A. Bill of purchase.

Q. Okay, bill of purchase. Did you ever wonder why it didn't come with any other piece of material that would explain risk or benefit?

A. No, I never wondered that.

Q. Do you wonder it now?

A. No.

Q. Why not?

A. Because when I contacted Jim Clark a few times, he told me that he works with the FDA and he's allowed to sell this machine, and he has no problems. The FDA has never been sued by, the FDA has never told him that he can't sell the machine.

Q. So am I understanding you to say therefore

* * * *

[3167] positive kinesiology test.

With a psychological or subconscious allergy, we say the word out loud and in some patients their arm goes weak. We're taught in the advanced course in NAET that this is how we test for psychological allergies.

Q. How do you know this to be true?

A. Doctor Nambudripad has been doing NAET for many years, and she has many case examples on this, and I took her word for it.

Q. So it's more anecdotal information rather than scientifically-based?

A. Yeah, it's more anecdotal or empirical, but I could see how it worked in the lie detector example this morning, AND how different words can influence the lie detector. People can call you a bad name or something, and all of a sudden you get a lot of nervous responses, so I could see how it could work.

I have never really done a lot of research on this. It only takes me a fraction of a second to say the word out loud. She taught us to do this in the advanced course, so I do it.

MS. PAXTON: Thank you, Doctor.

JUDGE DeBUSSCHERE: Doctor Uberoi, you

* * * *

[3169] Q. Okay –

A. I'm not going to have food in my office.

Q. So it's a kitchen area in the office?

A. Yes.

Q. And it's not an office in the home?

A. It's not an office in the home, no.

Q. The nurse, do you employ an R.N. L.P.N., the nurse who went to learn this machine?

A. She was a registered nurse.

Q. R.N.?

A. R.N.

Q. What was her role in learning the machine, what was she going to be doing after the training on the machine?

A. Originally I wanted her to basically teach me how to use the machine, until I had time to go in there and take a course myself. I knew I wouldn't have time to take a course right away, so I sent her down there to learn how to use the machine.

Q. Did you go and learn it yourself, or did you just learn from her, and that was –

A. I learned from her, the manual, and then the way I use the machine is not electrodermal screening. I do a different technique.

Q. Is the nurse still working with you?

* * * *

[3178] two, we check for antithrombin antibodies. We do a whole different blood cascade, because these patients have different coagulopathies. They can't get better unless their fibrinogen goes below 300 usually.

In some people with Chronic Fatigue Syndrome you might see fibrinogens around 600 or even higher, and it can be environmental, genetics. There is different causes for it. It affects organisms.

Q. So you put them on Heparin?

A. Not always. There's Nattokinase, an enzyme that lowers fibrinogen, there's curcumin.

Also detoxification of the body of heavy metals will also lower fibrinogen.

Q. So why was she so attached to the machine, rather than to the NAET therapy, because she said don't take my machine away from my doctor, then I won't be able to get my treatment?

A. The reason why, I can scan for hundreds of allergens in a 15-minute office visit, where if I didn't have the machine, I might only be able to scan for maybe half that amount, or even one-third that amount, and I might not find the allergen, so that patient wouldn't get a treatment that day, so the machine saves me a lot of time.

Q. My last question, when any patient comes to [3179] you, are they coming to you as an M.D. or as an NAET practitioner, I mean are they coming to you for everything, looking for –

A. They're coming to me usually from word of mouth. They already know that I'm an M.D. because it's on my door and it's on my business cards that I'm an M.D..

Q. So they come expecting that you will take care of everything for them?

A. No. No, I can't do that, that would be impossible. I mainly specialize in chronic fatigue states and allergies.

Q. So you cannot tell them that you will take care of them the best way you think will be best for them, like –

A. No, some –

Q. – nasal sprays and desensitization or NAET or acupuncture, or –

A. It depends on what their complaint is. If they come in with cardiac problems, they're definitely going to be referred to a cardiologist. If they have problems with sleep apnea, I refer them to a pulmonologist.

So if they come in for allergies, I do avoidance therapy. I give them antihistamines, [3180] steroid nose sprays, tell them to clean up their house and environment, and then I offer them NAET.

DOCTOR UBEROI: I'm done.

JUDGE DeBUSSCHERE: Thank you. It's now an opportunity for follow-up questions by the questions asked by the Panel members.

Mr. Bishin, do you have any follow-up questions?

MR. BISHIN: The only question I have is a question to everybody. My recollection was that Patient 3's testimony, and it may be wrong, is that she was concerned about losing her doctor, not losing the machine.

MS. PAXTON: Did I say that? I think in the end she did say, please don't take the machine away from him.

MR. TENNIS: Yes, she did.

DOCTOR UBEROI: She said please don't take my machine away from him.

MR. BISHIN: I guess I never heard that before.

MR. ARMSTRONG: She said it over and over.

DOCTOR UBEROI: Yes, she did. It was like she was so attached to the machine.

[3181] JUDGE DeBUSSCHERE: Any other questions, Mr. Bishin?

MR. BISHIN: No.

JUDGE DeBUSSCHERE: Mr. Armstrong, question, follow-up questions asked by the Panel members?

RECROSS EXAMINATION

*BY MR. ARMSTRONG*:

Q. Doctor Ames, let me see if this is your understanding, that assessment is equivalent to diagnosis when dealing with a patient?

A. There is a preliminary diagnosis doctors do when a patient presents with a complaint, and then

there is a final assessment that might be correct or incorrect, but that's what the doctor works on for his plan.

So I start with a working assessment and then I try to finalize it to a final assessment, but the final assessment could be wrong, but we can always do more blood tests to see if it confirms my assessment, or different testing.

Q. Where does the LISTEN machine come in, is it at the preliminary assessment or is it at the final assessment?

A. The LISTEN machine is more of a preliminary [3182] assessment. It's part of a preliminary assessment.

Q. If it's part of a preliminary assessment, don't you go straight to treatment with NAET?

MR. BISHIN: Be a little clearer, Counsel.

Q. I'm trying to find out where the LISTEN machine is in the scheme of your assessment. You're saying it's more in the preliminary assessment, but I think in your testimony – correct me if I'm wrong on this – that once you assess using the machine, which is quicker than using the vials, you go straight into treatment, which is NAET, correct?

A. Well, the assessment consists of a detailed patient history. The patient will usually tell me what their allergen is, or I'll be able to figure out from their history.

I also do blood work, okay, and then I do NAET testing using patient samples that they bring in, or the machine, and then I formulate a theory that they might have an allergy by muscle tests. I do kinesiology tests, and if their arm goes weak, then I can presume that they may have an allergy.

Q. Then you go into treatment, correct?

A. Then I go into treatment, and if their symptoms go away, that further helps my assessment. [3183] That tells me that they probably did have that allergy, because their symptoms went away.

Q. Okay. I think one of the board members asked you about the EAV system, Electroacupuncture Volt –

A. Voll, according to Doctor Voll.

Q. You were talking about making antigens, and you said that the LISTEN device can make vials, correct, did I get that correct?

A. The LISTEN machine can make antigens.

Q. How do you, as a medical doctor, know that it's correct and accurate, how do you know that device is making correct vials?

A. The reason I know that is because since I'm very skeptical, I have the patients bring in real foods or real pollens, and I'll type in milk, and they will bring in a glass of milk, and they get the same response with kinesiology testing.

The only time I would not get the same response might be house dust, because their house dust might have cat hair in it, for instance, the machine might have a different read, or molds, for instance. The machine holds about 80 different molds, because we know there's thousands of different molds, some haven't even been discovered, but besides

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**AMES v. WASHINGTON STATE DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION**

**On Petition for Writ of Certiorari to The Supreme Court of the State of Washington**
NO. 80644-6

**OBJECTIONS, ARGUMENTS, RULINGS, AND COLLOQUIES AMONG PRESIDING OFFICER AND COUNSEL**

**Clerk's Certified Report of Proceedings**
**1985-86, 2123-24, 2134-38, 2137-38, 2140, 2167-69, 2243-44, 2263-68, 2519-20, 2533-2535, 2542-45, 2547-49, 2551, 2556, 2569, 2575-76, 2648-49, 2680, 3019-20, 3200, 3205, 3213, 3217**

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[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

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| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | Docket No.<br>02-06-A-1012MD<br><br>DAY 1 |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

[2123] doctors are using it for, is that what you're saying?

Q. Yes.

A. What's your question?

Q. The question is if the item is not approved by the FDA or doctors you know, would you still use it for an alternative use? I'm saying aspirin is not approved. You can't use aspirin for any medical purpose in the United States, but you want to use it for another purpose.

MR. BISHIN: You can't use it or you can?

MR. ARMSTRONG: You cannot use it for headaches.

A. Doesn't that already say that aspirin is illegal for any doctor to prescribe?

Q. There are no doctors that use aspirin for headaches, that's my example, nobody uses it for any medical purpose whatsoever.

MR. BISHIN: Your hypothetical is aspirin is not being legally marketed?

Q. And you were going to use it for a different purpose than headache. Would that be an authorized use as a medical practitioner?

A. I would not use aspirin in that case.

Q. You would not. Okay, so if I understand you [2124] clearly, if it's not an approved product or a drug, you would not use it for a different use?

MR. BISHIN: Objection –

A. That's not what you said.

JUDGE DeBUSSCHERE: One second, Doctor. Objection to what?

MR. BISHIN: He said he would not use it for a different use, what different, different from what?

JUDGE DeBUSSCHERE: I'll sustain the objection, I'm not sure – objection sustained. The question is vague.

MR. ARMSTRONG: Maybe I'm just not being clear. I'll move on to another aspect of it.

Your understanding of off-label use, Doctor, is that it's something that needs to be approved, it can be used for alternative use for what it's approved for.

A. To use it for another use?

Q. As an general term. I'm just using it as a general term.

A. Yes.

Q. If the item is not approved, then off-label use doesn't apply, does it?

A. If the item is not approved by what

* * * *

[2134] Q. Look down at the bottom right-hand side, where it talks about inside range, outside range and reference.

A. I don't know where you're looking.

Q. Same document, the right side at the bottom.

MR. BISHIN: Your Honor, I'm objecting to this entire line of questioning. It has nothing to do with this case. There is nothing that's complained about lead or lead testing or any treatment for lead, or anything of that sort. It's completely irrelevant to this case.

JUDGE DeBUSSCHERE: Mr. Armstrong, I assume you were talking about the Department's case here on allergies. I thought maybe you were pursuing this on the vein that he was, his treatment with regard to allergies.

MR. ARMSTRONG: Yes, that is part of it. The Department's case is on his treatment with patient 1, period, not allergies only, all of the things he did. The patient's complaint was based on his treatment with Doctor Ames, not the LISTEN device of Doctor Ames. It was on all of his visits.

One of the things that the patient is going to testify about is metal toxicity and Doctor Ames' tests, what tests he didn't conduct, and [2135] whether that was above or below the standard of care, according to medical judgment.

MR. BISHIN: He's not going to testify over my dead body. That is not in the Statement of Charges, Your Honor. The regulations that govern this proceeding are very specific about specifically stating the factual basis on the Statement of Charges, and that is not in the Statement of Charges.

We did not prepare a defense to anything leading to that, although counsel is telling us that this is about the entire treatment, everything that went on.

That's not what the Statement of Charges is about. Everyone here can look at the Statement of Charges and see what the Statement of Charges refers to. It refers to this device and to the muscle testing that went on, and to some statement allegedly made, and to the FDCA implications of this particular device.

There is nothing about lead testing or any other kind of treatment, or anything else in the Statement of Charges.

MR. ARMSTRONG: Your Honor, may I respond?

JUDGE DeBUSSCHERE: You may respond.

[2136] MR. ARMSTRONG: Contrary to what counsel is alleging here, paragraph 1.13 of the Statement of Charges talks about the different tests that Respondent ordered, urine, blood and hair analysis tests. That is in the Statement of Charges. Clearly the evidence that is going to be presented will address those factors.

What the Department is alleging is that everything that is listed in the Statement of Charges falls under the negligent practice, and falls below the standard of care.

It doesn't tell you exactly every single detail, because the Statement of Charges doesn't need to do that. We just need to give the Respondent a general basis of what our charges are.

JUDGE DeBUSSCHERE: Okay. The charge is based on the Respondent's use of the LISTEN device, and that is unprofessional conduct as alleged in RCW 18.130.184. There is no allegations here that he, and I put that in my pre-hearing order, that his use of the hair analysis was unprofessional conduct.

MR. ARMSTRONG: If you look at 2.2.

JUDGE DeBUSSCHERE: You said that all of these, some of these alleged facts are conclusions of law. They're not facts at all, and so I cannot, the [2137] way the charges are written alleges that the Respondent committed unprofessional conduct using this machine, this LISTEN device, and particularly in his diagnosing and treating food allergies, this patient's allergies.

There's no other allegations of unprofessional conduct regarding any other mistreatment. The fact and the allegations that the Respondent ordered urine, blood and urinalysis tests is not notice that he committed unprofessional conduct under RCW 18.131.184 on that alone, and I said that in my pre-hearing order.

You yourself said in your opening statement that this is a matter of food allergies, whether or not there was unprofessional conduct with food allergies.

I thought your line of questioning that to do with Doctor Ames, questioning him in regards to providing treatment for food allergies, not the fact that he is going to be charged for, I think you were talking about lead poisoning. That point wasn't alleged and that is not part of the statement of charges here.

If he was charged with lead poisoning for this patient it should have been stated in the [2138] Statement of Charges.

MR. ARMSTRONG: Would you like me to respond?

JUDGE DeBUSSCHERE: You don't need to respond. I made a ruling. The objection is sustained.

MR. ARMSTRONG: Well, I'd like to make an offer of proof.

JUDGE DeBUSSCHERE: You may make an offer of proof.

MR. ARMSTRONG: On the record, under 2.2 in the Statement of Charges, 1.1 through 1.13 are the factual allegations. It says in 2.2 that –

MR. BISHIN: Your Honor, I object. This is not an offer of proof, this is further argument. An offer of proof is an offer of evidence. You're showing the tribunal what evidence you would have introduced if you had been allowed to do so. This is just further argument and it's typical of what counsel does, continually re-arguing and wasting everybody's

time, arguing and re-arguing the same point. This has been going on throughout this entire proceeding.

JUDGE DeBUSSCHERE: Mr. Armstrong, Do you have your offer of proof?

* * * *

[2140] have not changed one bit of our evidence, it's just that he is uncomfortable with how the question is coming out.

MR. BISHIN: I object again. This is not an offer of proof. Even if it were an offer of proof, it's not necessary. What he's pointing to is the Statement of Charges.

The Statement of Charges is on the record, it's right there. An appellate court can see the Statement of Charges without any statement or argument by counsel.

JUDGE DeBUSSCHERE: I have made my ruling. Lead toxicity is not part of the charges, as I have stated in the Statement of Charges. Next question.

Q. Doctor Ames, I want to go back to the LISTEN device itself, and how you use it. You don't use it as an EDS, Electrodermal screening, you don't use it for that purpose?

MR. BISHIN: I object, asked and answered.

MR. ARMSTRONG: I'm trying to get an undertanding.

JUDGE DeBUSSCHERE: It has been asked and answered.

* * * *

[2167] Paxton, do you have questions?

MS. PAXTON: I do, but I want clarity first from you, JUDGE DeBUSSCHERE.

JUDGE DeBUSSCHERE: Okay.

MS. PAXTON: I want to go back to the First Amended Statement of Charges, because I never did get clarity, and the attorneys may say asked and answered, but I'm sorry, that doesn't go for me, and so excuse me, gentlemen, but I have to ask this again.

In 2.2 it talks about the facts alleged in Paragraphs 1.2 through 1.14. as that which constitutes unprofessional conduct, so I need help once again, to understand why you excluded 1.13 as not part of that which constitutes unprofessional conduct.

JUDGE DeBUSSCHERE: I didn't exclude 1.13 as a fact. It was a fact that was alleged, but the allegations alleged that there was conduct that was unprofessional under RCW 18.131.84, incompetence, negligence, malpractice with results causing injury to a patient, which creates an unreasonable risk that the patient may be harmed.

The fact that the Respondent ordered urine, blood, blood tests, hair analysis tests is a [2168] factual allegation, but there is insufficient facts there

to notify the Respondent that the fact that he ordered a urine test is unprofessional conduct, or the fact that he ordered a blood test is unprofessional conduct, or the fact that he ordered a hair analysis, or a combination of those.

There is insufficient information in the Statement of Charges to give notice to the Respondent that such conduct was unprofessional.

The substance of the Statement of Charges references that the patient used the LISTEN device, and such conduct was unprofessional. If I were to allow, if the Statement of Charges had more information, in fact, stated that the Respondent's conduct in giving blood tests or urine tests or hair analysis, such conduct created a certain kind of harm or was below the standard of care in the allegations, there would be sufficient notice for the Respondent to be able to defend himself against those allegations.

At this point in time the document itself is insufficient to give notice to the Respondent to defend himself, to do discovery, cross-examination to prepare for this case by the Statement of Charges, so that's the reason why I made that ruling.

* * * *

[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

| | |
|---|---|
| In The Matter of the License To Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent. | Docket No. 02-06-A-1012MD |

VERBATIM TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

APPEARANCES

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Suite 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 14, 2004

Reported By
Duane W. Lodell
CCR #
LODELDW533N9

ROBERT H. LEWIS
& ASSOCIATES
Certified Court Reporters
5113 Pacific Highway East,
Suite 1
Fife, Washington 98424-2639
253.952.2030 – 1.877.952.2030
*Fax: 253.927.2520*



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[2263] ***Patient 1 – By Dr. Uberoi***

We'll tolerate this for a little bit. Then, we may have to go see about it. Go ahead.

Q (By Dr. Uberoi) He didn't tell you what the benefit or reasoning was for the kelation therapy?

A The benefit, as I understood it –

JUDGE DeBUSSCERE: Excuse me. I don't think we can hear. Let's go off the record.

(Pause in the proceedings.)

Back on the record.

We were able to stop that intervening noise from adjacent rooms.

Go ahead, Dr. Uberoi. You were asking questions.

DR. UBEROI: I was asking if Patient 1, whether he was told anything about benefits or side effects or risks of kelation therapy.

A The benefits, as I say, were explained to me to be linked with the heart and the arteries and that, and actually cleaning out a lot of plaque, things like that. That's kind of what I recall would be the main benefits, kelate the toxins out.

Q Were you told about any risks of kelation?

A No, no, no.

DR. UBEROI: I'm done.

JUDGE DeBUSSCHERE: Ms. Paxton, do you have any questions.

[2264] MS. PAXTON: Just one second, Your Honor. Thank you.

***Patient 1 – By Ms. Paxton***

EXAMINATION

BY MS. PAXTON:

Q Patient 1, there seems to be some question in terms of what is a focus of this hearing as to your treatment regarding, you know, the allergy issue versus the heavy-metal issue. There's some controversy

about that issue. So I want to ask you some specific questions about that.

MR. BISHIN: Objection, Your Honor. I hear these questions about kelation. You allowed questions about the kelation, about the hair test and all that kind of stuff. But those are not in this case. If this was going to be a case about hair test or kelation, we would have prepared a case for hair test and kelation. It's known from the beginning that this was not what this case was about. Now, we're extending it beyond that. Dr. Uberoi started asking questions about kelation, too.

Now, if it's background, that's fine. But we're going beyond that. Ms. Paxton also seems to want to go beyond that. And I can understand being interested and maybe having opinions on the subject and all of that, but that's not what this case is about. This is a legal [2265] procedure, involves what we call due process of law. Requires notice and opportunity for hearing and the charges that were noticed.

And going on, counsel for the Department of Health has been trying to move this from what the case was always focused on to something else for a while now. But this is highly prejudicial, and I object very strongly to continuing going into this. It's not a matter of controversy as to whether this case is about hair testing, kelation or about allergies and the LISTEN machine. That issue has been resolved. It's not controversial at all. The issue is about the

LISTEN machine and about food allergies and how they were tested for in this particular situation and whether or not the Food, Drug and Cosmetic Act has any application to this particular case.

That's my position, and I believe it's correct, and it will be supported by the record of this entire proceeding, going back to the very beginning of the statement of charges.

MS. PAXTON: Can I respond, for a moment, just in terms of the information?

JUDGE DeBUSSCHERE: You mean, as far as asking questions?

MS. PAXTON: No.

[2266] JUDGE DeBUSSCHERE: Do you have a question –

MS. PAXTON: I guess I had a question for you, then.

JUDGE DeBUSSCHERE: Yes.

MS. PAXTON: It is on the record that Patient 1's chart notes from two visits are here and present, and those have been addressed. Therefore, I presume it's acceptable to ask questions from the material that we already have received.

JUDGE DeBUSSCHERE: You can ask questions about the material that is received.

MS. PAXTON: And it's shown in the second visit a plan that Dr. Ames outlined.

JUDGE DeBUSSCHERE: You mean, in paragraph 1.14 of the statement of charges?

MS. PAXTON: No, in the document marked 2, on page one, Exhibit 2, page one, there's a plan.

JUDGE DeBUSSCHERE: You can ask questions about that.

MS. PAXTON: And that's sort of the direction I'm going.

MR. BISHIN: Objection, Your Honor. I want to object very strongly to that.

Of course, you can ask questions from documents on [2267] the record if they are relevant to the issues before this panel. The entire medical record was put in here, in this particular case, so that the panel and the record would be complete and there would be context. But that doesn't mean that you can go into every possible issue that's raised by what's in those records.

This is a case not about the entire treatment that went on here or the entire recommendation or the entire notes, but about particular things that the department chose to talk about in the statement of charges. That's what the case is about.

So of course they can ask questions, as long as they are related to the issues, as long as they are relevant. And anything, anything that's on the record,

Ms. Paxton or anybody else can ask questions about, just as counsel can ask questions about. But when you are pursuing issues about kelation or hair test or anything else that are not what this case is about, then it's irrelevant and it's also prejudicial.

JUDGE DeBUSSCHERE: Ms. Paxton, the reference on 1.13 describes that he had a visit on June 6, the respondent saw Patient 1. Then, 1.14 focuses on the respondent diagnosing food allergies, the use of the LISTEN device. That's what the charges are about.

[2268] But you can ask questions about the plan, you can ask questions. But the context here is within the issue of was his use of that medical device, was it unprofessional conduct under the allegations.

MS. PAXTON: I understand, Your Honor.

JUDGE DeBUSSCHERE: Was it negligence, did he violate federal and state statutes and was it moral turpitude or did he promote for personal gain any unnecessary device, unnecessary or inefficacious device. So that's the issue here. You can ask questions about other things, but put it in the context of that.

MS. PAXTON: Thank you for your clarity.

Q (By Ms. Paxton) I want to ask you, Patient 1, about your treatment for your allergy. Basically, from the tests that we have talked about before, some of the allergies that stood out over others in terms of the numbers.

A Right.

Q You had stated before that you basically had been told by Dr. Ames that you were going to walk out of his office after the second visit and be cured of your egg allergy; is that correct?

A Correct.

Q And that was after what you considered a treatment that occurred in the office?

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[2519] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

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|---|---|
| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br><br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br><br>Respondent. | Docket No. ___<br>02-06-A-1012MD<br><br>DAY 3 |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[2533] reasonable risk of harm to the public.

Now the classifications make a big difference on how the machine is used. If you have an approved device by the FDA, then you can use it. Basically that's it. If you use it for an alternative use other than what is labeled, which is what has been bandied about as off-label use, that happens all the time in the medical field, but if you're not approved you can't have an alternative use, because if you're not approved you have no use.

It's kind of like not being on the playing field. You can't play a different game if you're not even on the field, and that's what the defense is trying to convince this Panel that they can play an alternative use game, and they're not even allowed on the field. It will not work. The FDA confirmed what my argument was, that an approved device can have an off-label use, but an unapproved device cannot, and this device is unapproved.

We looked at the use. We did ask, Mr. Bishin asked Mr. Ogden about the intended use of the device. Well, the FDA looks at the labeling to determine what the intended use was, not what you plan to do afterwards, not five years from now, but how you plan on using it when it's time to sell it. [2534] That's the use that's on the label, and that's what they go by is an objective concrete criteria. It's

not a changing criteria, it's not a range of criteria. You have to have the intended use on the labeling, with the information that goes with it. If you don't have that, you won't pass the muster of the evaluation.

Well, the LISTEN device, based on this labeling saying what it can do, what its capabilities are, did not pass muster with the FDA, which is the only place it must pass the muster in order to be distributed. What makes this even more serious is it shouldn't even be marketed in the United States. If it's not cleared, it shouldn't be marketed. Now people can buy contraptions all day long everywhere, but you can't use them in practice if it's not cleared by somebody who says it's safe and effective.

This device has not been cleared. This device was marketed. This device was received. The device was received by Doctor Ames. He said he bought it in 1997. He didn't buy it overseas. He bought it here. Receiving a device that's not been cleared violates the statute. There's no question about that.

So as Counsel keeps harping on the [2535] burden that the State has, and I agree we have the total burden here, I'm making the argument on two grounds. One I'm arguing that the burden of proof is not clear and convincing. I'm saying it's the preponderance of the evidence, as the statute says, but because of the case law that has come down recently, we do have an indication that it could be, so I'm

asking you, Panel, to look at my statements under a preponderance of the evidence and a clear and convincing evidence, but I'm going to make my comments in the purview of absolutely clear and convincing, so that you will have no problem on either burden, on the fact that he received a device that was not cleared, violating the State and federal statute is clear. It's a hundred percent. There's not even a doubt on that. Whether this device has been proven safe or effective, there's no evidence. Therefore it's clear. That's a hundred percent.

If he had clearance, he would have a document from the FDA. Now the FDA can't just tell you that you're cleared for your device. They have to give you a document, and you must possess that document in order to receive clearance.

I asked Doctor Ames does he have any written proof from the FDA that this machine is safe

* * * *

[2648] care, because they're experts.

Now, as I say, I can't believe that would be upheld today by the supreme court in a case like this where the Commission is not expected to have any kind of expertise on alternative health care, or on these particular devices. They will have general knowledge about medicine, have general knowledge about health care, but they don't have any evidence on this kind of a device, or on the particular use of acupressure with regard to allergies, or a lot of other things.

We do not believe that the courts would uphold that, it just wouldn't make any sense. How could you defend yourself? There's no evidence put on these issues, and it just goes back to the Commission that later on, after they make the decision, find out what standards they applied in that particular case, but forgetting about all that, one thing that you have to keep in mind here is that even though the court in Johnston said that it wasn't necessary to have a standard of care when it's a physician, since the physicians on the Panel could have rejected it and used their own experience, that only went to standard of care. That only went to standard of care. It did not go to any other issue.

[2649] Although the general law is there must be evidence on the record on which the decision is based, even though inferences can be drawn based on general medical knowledge, there must be evidence on the record, and that evidence must be sufficient to support the decision of this commission. That's A, in fairness to the Respondent.

B, it's essential for the courts to be able to review the decision of the commission. You can't review a decision if you don't have evidence in the record to support it. If there is no evidence to support it and it's hidden evidence that the Panel is relying on, then they can't review it, and there is a specific provision of the Administrative Procedures Act says that every single finding of fact must be supported by evidence on the record. There must be evidence on the record.

The only area where an exception has been made is the standard of care, and that standard of care is often viewed as a legal battle. I say that because in order to find a violation against Doctor Ames, you have to find unreasonable risk or actual harm, and there has been no evidence of unreasonable risk or of actual harm. No one has testified to that here. There is speculation that

* * * *

[2680] the evidence that was presented up to this point, after which the Respondent had rested, and the evidence presented by the Department.

Regarding the Respondent's motion to Dismiss, regarding the alleged violation of RCW 130.180, RCW 18.130.180 Provisions 1 and 7, the Commission granted the Motion to Dismiss.

Regarding the provisions RCW 18.130.180, 4 and 16 the Commission denies the Motion to Dismiss.

The Respondent here is now instructed to present evidence in response to the allegations of RCW 18.130.184, RCW 18.130.180, Provisions 4 and 16.

MR. BISHIN: So that's four and 16 that's still in the case?

JUDGE DeBUSSCHERE: Yes.

MR. BISHIN: Now, I'd like to – I'm sorry, Your Honor, are you done?

JUDGE DeBUSSCHERE: Yes, I have reported the decision on the Motion to Dismiss.

MR. BISHIN: I'd like to raise a couple of issues, procedural issues. One of my telephone witnesses should probably be called soon, in order to be sure that we get him on, but there is another matter that I want to raise and I don't want to have it waived by my calling this witness.

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[3019] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

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|---|---|
| IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF:<br>GEOFFREY S. AMES, M.D.<br>License No. MD00026961,<br>Respondent. | Docket No. 02-06-A-1012MD<br>DAY 5 |

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:

ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:

WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:

KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.,
Public Member

Renton, Washington
February 10, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[3200] during their deliberations.

Okay, so we'll go into recess.

(A recess was taken.)

JUDGE DeBUSSCHERE: We're on the record.

It's now an opportunity for closing argument. This is in the matter of the license to practice as a physician and surgeon of Geoffrey Ames.

Mr. Armstrong, go ahead. You have about 25 minutes.

* * * *

CLOSING ARGUMENT

*BY MR. ARMSTRONG*:

I want to thank the panel for their indulgence in this case. Knowing that we have a whole bunch of doctors in this state that we could be going after, why is the Department going after Doctor Ames for his use of the LISTEN?

It's a few words why. We don't know if the machine is safe, and neither does he. That's why we're going after Doctor Ames.

And to determine this you have a lot of witnesses that were here determining whether he committed misconduct under the rules, and it's going to come down to credibility. A lot of things were said, and most of them were facts, as to who do you

* * * *

[3205] the treatment of allergies.

Doctor Ames said he never treated Patient 1. It's really curious, again, that the treatment that Patient A described was exactly the same as Patient 3, the exact treatment, the same thing, where he was on his stomach, while he was on his back, and using that machine.

Doctor Ames said today he never used any device on him, but the patient remembered a black, some kind of device on his back thumping him. He remembered it was different than the one that was sitting right beside him, but even Doctor Ames confirmed that he had a manual, so electronic, so Doctor Ames' own rebuttal confirmed what the patient said, not what he said, but what the patient said.

We have asked Doctor Ames and all his witnesses, can the LISTEN machine diagnose? No. Can it cure? No. Why do you use it? It helps me. It makes me faster, more effective, more comprehensive. To do what? You're either using it to diagnose or cure; otherwise, it has no use. The Department yesterday, it has no use, which is why it's inefficacious, which is why it's unknown, and it's why the FDA hadn't cleared it.

He mentioned, Doctor Ames mentioned that

* * * *

SUPERIOR COURT FOR BENTON COUNTY
STATE OF WASHINGTON

| | |
|---|---|
| GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN., Respondent. | NO. 04-2-01837-1 **PETITION FOR REVIEW** (Filed Aug. 16, 2004) |

Petitioner Geoffrey S. Ames, M.D., by and through his attorneys, Law Offices of William R. Bishin, Inc., P.S., hereby petitions for review of a final order, an order denying reconsideration of that order, and all previous orders adverse to him entered in the proceeding below by Respondent Medical Quality Assurance Commission.

## 1. IDENTITY OF PETITIONER

Petitioner Geoffrey S. Ames, M.D., an alternative physician providing health care based on the principles of acupuncture, acupressure, homeopathy and other nontraditional forms of health care, practices and resides in Benton County, Washington with a mailing address of 750 Swift Blvd. No. 1, Richland, WA 99352.

## 2. IDENTITY OF ATTORNEY FOR PETITIONER

William R. Bishin, Inc., P.S. by William R. Bishin, Esq., WSBA No. 8386, represents Petitioner in this matter and has a mailing address at 1404 East Lynn, Seattle, WA 98112.

## 3. IDENTITY OF AGENCY WHOSE ACTION IS AT ISSUE

The agency whose action is at issue is the Washington State Department of Health Medical Quality Assurance Commission ("MQAC"), 310 Israel Road S.E. Tumwater, WA 98501.

## 4. AGENCY ACTIONS AT ISSUE

The Agency actions at issue are the Findings of Fact, Conclusions of Law and Final Order ("Final Order"), dated May 30, 2004 and served June 4, 2004, the Order Denying Petition for Reconsideration, dated July 18, 2004 and served by mail on July 19, 2004, and all other orders and rulings entered by Respondent in the course of the proceedings below to the extent they were adverse to Petitioner, including the order denying constitution of a panel including alternative physicians and the order excluding the majority of Petitioner's proposed witnesses.

The Final Order finds that Petitioner was guilty of unprofessional conduct under 18.130 RCW – i.e., negligence and promotion for personal profit of an

inefficacious modality – in that he used a device which it found to be inefficacious in the assessment and treatment of an allergy of a particular patient. The Order suspends and then stays the suspension of Petitioner's license on the condition that he refrain from using the device, levies a $5,000 fine and enacts a program of monitoring for five years, ostensibly to assure that the device is not used in Petitioner's practice.

The Order Denying Petition for Reconsideration rejects petitioner's claim that the Final Order is devoid of evidentiary support, is an abuse of power by orthodox physicians with respect to an alternative practitioner, and flagrantly and lawlessly disregards controlling Supreme Court authority and statutory mandate.

## 5. PARTIES IN PRECEDING ADJUDICATIVE PROCEEDINGS

(RCW 34.05.546)

There were no such parties, other than the Department of Health and the Commission, insofar as it is a separate entity as represented by the Attorney General.

## 6. FACTS DEMONSTRATING THAT PETITIONER IS ENTITLED TO OBTAIN JUDICIAL REVIEW

The Order directly, substantially, and lawlessly, deprives Petitioner of liberty and property not only by inhibiting his successful practice of alternative health care but also by stigmatizing him with a record of a suspended license that will seriously affect his ability to practice in any form, all in violation of 34.05 RCW, 180.130 RCW, and other statutes and of the United States and Washington constitutions and is a final action by an agency covered by the Administrative Procedure Act, 34.05 RCW, and under which Petitioner has an absolute right to seek judicial review. Petitioner contends that he is entitled to relief under several subsections of RCW 34.05.570(3) as more fully described below.

## 7. REASONS WHY PETITIONER IS ENTITLED TO RELIEF

RCW 18.130.180(4) (second sentence), as its legislative history makes plain, was enacted to protect alternative ("nontraditional') physicians from the prejudices of orthodox, old-line medicine – prejudices which continue to infect the work of medical boards throughout the United States generally and, as this case shows dramatically, of MQAC in Washington, specifically. In addition, the Supreme Court of Washington recently imposed a more demanding evidentiary burden on MQAC because, *inter alia*, of concern that the risk of erroneous MQAC decisions

was greater than the risk of, for example, erroneous court decisions in civil cases involving medical issues. See *Nguyen v. Medical Commission*, 144 Wash.2d 516, 29 P.3d 689 (2001).

With all the respect that is due to a coordinate branch of government, Petitioner contends that the final order entered in this case by MQAC – which contains no practitioners of alternative medicine, either in its regular or its pro tem membership – is not only a breathtakingly arrogant attempt to circumvent both the letter and the spirit of RCW 18.130.180(4) and of the *Nguyen decision*, but a refusal to honor the most elementary principles of evidence law and, at bottom, of due process. The Final Order violates DOH and MQAC regulations, 34.05 RCW, the Administrative Procedure Act ("APA"), as well as 18.130 RCW, the Uniform Disciplinary Act ("UDA"), other statutes and the constitutions of the State of Washington and of the United States.

The Final Order finds that Petitioner in the course of providing an alternative form of care for allergies was guilty of negligence creating an unreasonable risk of harm and of promoting an inefficacious health care device and modality. The Department of Health, however, was unable to produce any evidence to establish harm of any kind, let alone "unreasonable harm." Nor did it produce evidence of inefficacy or any of the other distinguishing elements of the statutory violations charged. *Nguyen* requires that MQAC orders be supported by

*clear and convincing* evidence, but as to essential elements of the two charges of unprofessional conduct upheld by the MQAC panel in this case, it bears emphasis that there was no evidence at all, let alone substantial or clear and convincing evidence. In addition, the panel disregarded uncontroverted and incontrovertible evidence in medical records that the Department itself introduced, records which directly contradict essential findings in its Order.

The flagrant disregard of evidentiary rules establishes that the panel in this case was intent on prohibiting the use of an alternative modality in which it did not believe, based only on the prejudices of its members against alternative care, and irrespective of the evidence. In so doing the panel unapologetically ignored controlling rules of procedure and proof, DOH and MQAC regulations, the APA, the UDA and other statutes, and the requirements of the state and federal constitutions. The panel thus not only entered an order that was illegal, it displayed illegal and unconstitutional prejudice against Petitioner, demonstrating that it was not qualified to decide this case dispassionately. Among other things, it thereby engaged in unlawful decisionmaking and showed itself to be improperly constituted. All of this was in violation of the APA, the appearance of fairness doctrine and the constitutions of the State of Washington and of the United States.

The panel erred when it refused to dismiss all charges after the close of the Department's case even though it was clear that the Department had failed to

offer evidence to support a violation of the UDA. The panel erred when it entered the Final Order, and it erred when it refused to reconsider that order after Petitioner expressly pointed out for the last of several times the fatal evidentiary flaws in the Department's case.

The Final Order on its face is defective because it does not satisfy specific requirements of 34.05 RCW regarding the contents of such orders and does not provide the support in evidence and reasoning that the statute requires. If, as Petitioner contends, the Department failed to present evidence that could support the legal and factual findings in this case, it is, of course, not surprising that the Order does not set forth the support that the APA requires.

The Final Order finds a violation that was not charged, thereby violating Department of Health and MQAC regulations, the APA and the constitutions of the United States and the State of Washington.

The Final Order was entered after a hearing in which Petitioner was not permitted to call witnesses to testify to the efficacy of his allergy treatments and of his use of kinesiology in conjunction with use of the challenged device, thereby denying Petitioner the right to present his case and to establish his defense, all in violation of DOH and MQAC regulations, the APA and the constitutions of the United States and Washington. The orders denying him these and other rights to introduce relevant evidence violated the

same regulations, statutes and constitutional provisions and are challenged on this appeal as well.

The Final Order instituted sanctions that are an abuse of discretion, requiring monitoring of Petitioner that is unwarranted, arbitrary and capricious, and calculated to deter Petitioner from engaging in legal alternative health care modalities because of the uncontrolled supervisory and monitoring discretion which the Order gives MQAC to inspect and oversee his practice for at least five years.

The Final Order was entered by a panel which contained no physicians or other health care providers who practice alternative medicine, after Petitioner moved for inclusion of one or more such practitioners in the panel prior to the hearing. On the other hand, comments at the hearing betrayed the panel's prejudice against alternative practice. The Final Order either itself or in connection with the other unlawful acts and omissions of the Department and the panel thus violated the appearance of fairness doctrine, the APA, the UDA, and the due process protections of state and federal constitutions.

Among other things, the Final Order violates freedom of expression, due process, equal protection, personal autonomy and other rights protected by the constitutions of this State and of the United States.

The Order Denying Petition for Reconsideration is objected to on the same grounds as the Final Order.

Among other things, Petitioner is entitled to relief under RCW 34.05.570(3), because "(a) The order, or the statute or rule on which the order is based, is in violation of constitutional provisions on its face or as applied; . . . (c) The agency has engaged in unlawful procedure or decision-making process, or has failed to follow a prescribed procedure; (d) The agency has erroneously interpreted or applied the law; (e) The order is not supported by evidence that is substantial when viewed in light of the whole record before the court [nor, *a fortiori*, by clear and convincing evidence], which includes the agency record for judicial review, supplemented by any additional evidence received by the court under this chapter; . . . (g) A motion for disqualification under RCW 34.05,425 or 34.12.050 was made and was improperly denied or, if no motion was made, facts are shown to support the grant of such a motion that were not known and were not reasonably discoverable by the challenging party at the appropriate time for making such a motion; (h) The order is inconsistent with a rule of the agency . . . [and the agency has not explained] the inconsistency by stating facts and reasons to demonstrate a rational basis for inconsistency; . . . [and] (i) The order is arbitrary or capricious."

Because the transcript of the hearing and the voluminous record in the proceeding below have not yet been prepared, Petitioner also seeks relief for all other prejudicial errors which the transcript and the record show to have occurred, on the grounds that he

is entitled to relief for any errors that were prejudicial to him or his case.

## 8. RELIEF REQUESTED

Petitioner requests that the Court reverse the Order in its entirety and dismiss the proceeding below or in the alternative reverse and remand to the Commission with instructions to act in accord with the Court's decision and to dismiss the proceeding.

DATED: August 14, 2004

LAW OFFICES OF
WILLIAM R. BISHIN, P.S.

By /s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386

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## CERTIFICATE OF SERVICE

The undersigned caused the foregoing Petition for Review to be served upon Respondent Medical Quality Assurance Commission and the Attorney General by arranging for its delivery to them on August 16, 2004 at the following addresses:

Medical Quality Assurance Commission
310 Israel Road S.E.
Tumwater, WA 98501

Keith D, Armstrong, Esq.
Assistant Attorney General
6th Floor, Highways-Licenses Bldg
P.O. Box 40100
Olympia, WA 98504-0100

August 14, 2004

/s/ *William R. Bishin*
WILLIAM R. BISHIN
WSBA NO. 8386

COURT OF APPEALS, DIV. III **NO. 248976**

SUPREME COURT OF
STATE OF WASHINGTON

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**GEOFFREY S. AMES, M.D.,**

Petitioner,

vs.

**WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,**

Respondent.

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# PETITION FOR REVIEW

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(Filed Sept. 4, 2007)

William R. Bishin P.S.
1404 East Lynn
Seattle, WA 98112
(206) 323-7175
By: William R. Bishin No. 8386

Certificate of Service
The undersigned served this Petition on Respondent on this date by placing it in the U.S. MAIL addressed as follows:

Kim O'Neal, Esq.
P.O. Box 40100
Olympia, WA 98504

September 4, 2007

/s/ *William R. Bishin*

## IDENTITY OF PETITIONER

The Petitioner is Geoffrey Ames, M.D., the petitioner below.

## OPINION OF THE COURT OF APPEALS

The unpublished opinion of the Court of Appeals in this matter, Ames v. Medical Board, No. 24897-III was filed, by the Court on May 17, 2007. After Petitioner's timely motion for reconsideration, the Court entered an order denying the motion for reconsideration on August 2, 2007. The opinion and order are attached. See Appendix.

## ISSUES PRESENTED

The specific issues of constitutional, administrative, professional disciplinary and other, statutory law that this case raises are set out below. But there are issues that deal with the broader supervisory role of this Court in insuring that every person receive due process and that the outcome of every case comports with the Rule of Law. The appellate issues raised by this case arise out of the most brazen, lawless administrative action that counsel for Petitioner has encountered in over forty years of practice and teaching – including the teaching of administrative law – in jurisdictions throughout this country. The case is a frivolous, malicious prosecution, brought to coerce a settlement. It was prosecuted without evidence, yielding a decision, based on a series of patent speculations and ad hoc

factual theories created during and after the evidentiary hearing in this case.

Respectfully, and with a vivid awareness of and concern about the emotional resistance of judges to criticisms of their friends and colleagues on other courts, it must also be said that the agency's lawlessness in this case has been aided, abetted and implemented by the most striking abdication of judicial responsibility that counsel has encountered in the State of Washington, after almost thirty years of practicing here.

In short, the Court of Appeals refused to grant Petitioner the judicial review of agency error, to which he was entitled under the Administrative Procedure Act and the due process and equal protection clauses. As this and other courts have held, because of the needs of the administrative state, judicial review is the only protection against agencies with peculiar opportunities to engage in uncontrolled abuse, because they have been delegated and can combine in abusive ways the legislative, administrative, investigative, prosecutorial and adjudicative powers.

Not only does the Court of Appeals opinion in this case – and the oral, argument which preceded it – suggest that it did not seriously review the evidentiary record, the findings, or Petitioner's brief; not only does that court fail in all but one minor instance to cite even one place in the record which supports its affirmance of agency findings that

Petitioner vigorously challenged; but the Court of Appeals (borrowing not from the record, but from the agency brief) actually creates facts out of whole cloth and shifts the burden of proof to the Petitioner. It not only misstates the facts, but it bases its justification of the agency's conduct on findings that were never made and facts that do not exist. Like the respondent's brief, which it apparently viewed as the only document it need pay any serious attention to, that court also justifies the agency decision, not by defending the reasoning of the agency, but by creating a new, after-the-fact theory. The result is that the statement of charges proceeded on one factual theory, the panel's Order on another, and, the Court of Appeals's on yet another. Compare the allegations in the amended statement with ¶¶ 1.25-1.29 of the challenged Order with pages 10-14 of the Court of Appeals opinion, all of which appear, in the appendix. See Opening Brief ("OB") Appendix and this Appendix.

The outrageous decision of the agency was not surprising, because similar agencies throughout the country have done similar – although not quite as brazen – things in similar cases. But in those other jurisdictions, the Courts would not stand for it, and found a way to thwart the abuse of legislative power. See, especially, *Painter v. Abels*, 998 P.2d 931 (Wyo. 2000), where a medical board attempted to prevent an alternative physician from using a device like the one in this case by attacking her mental health and when that failed by claiming negligence without being able to offer any expert testimony to support

the claim. It is more than ironic that in Washington, where public policy is clearly opposed to the substantive objective which motivated the agency's action, the courts simply deferred to the agency's abuse and then defended it in disingenuous opinions.

There follow some of the specific issues this appeal raises.

1. Was the Medical Commission ("MQAC") panel that issued the Order on appeal correct in ruling that under existing Washington law no expert evidence on the record was necessary to establish the medical, scientific, or technical, facts on which its decision rests, and if the panel was correct, should those decisions, as to that issue, be overruled or limited on due process or other legal grounds?

2. Under WAC 246-11-250, WAC 246-11-260 and WAC 246-11-520, which requires that a statement of charges must contain a "clear and concise statement of the . . . factual basis" of the charges, must the statement set forth the specific facts – including the specific conduct of the respondent – found to constitute unprofessional conduct or is notice pleading sufficient?

3. Did MQAC's failure to specify in the statement of charges facts that it found essential to its conclusion that Petitioner had engaged in unprofessional conduct – including the specific conduct of the respondent which allegedly constitutes such conduct – violate his "due process right to be notified of clear and specific charges and to be afforded an

opportunity to anticipate, prepare, and present" his defense. *In re Romero,* 152 Wash.2d 124, 94 P.3d 939 (2004)?

4. May a physician be found to have engaged in "negligence" under RCW 18.130.180(4) because of a good faith mistake in judgment on one occasion without explicit evidence on the record that the mistake violated a standard of care which makes such a mistake negligence?

5. Under RCW 18.130.180(16) which makes "promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service" "unprofessional conduct,"

(a) is evidence and/or a finding that a device failed to function successfully on one occasion sufficient by itself to support a finding or a conclusion that the device is "inefficacious" within the statute's meaning?

(b) is the use in his practice of an alternative assessment device for which the respondent does not charge and which was not shown to increase his income, "promotion for personal gain" of that device within the meaning of the statute, taken as a whole and considering the consequences?

6. Were the proceedings below taken as a whole so outrageous and inconsistent with due process and the Administrative Procedure Act as to require this Court to lay down specific guidelines for the initiation, and conduct of medical commission hearings, at least

in cases involving alternative physicians and alternative medical, modalities?

7. Did the Court of Appeals and the Superior Court accord the Petitioner meaningful .judicial review of the panel decision in this case – *e.g.*, of his right to a determination of the sufficiency of the evidence under the Administrative Procedure Act and the due process clause?

## STATEMENT OF THE CASE

This case arises out of the use by a holistic physician of an assessment device which was found to be inefficacious and its use therefore a violation

* * * *

NO. 80644-6

SUPREME COURT OF
STATE OF WASHINGTON

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**GEOFFREY S. AMES, M.D.,**

Petitioner,

vs.

**WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,**

Respondent.

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# PETITIONER'S MOTION FOR RECONSIDERATION

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William R. Bishin P.S.
1404 East Lynn
Seattle, WA 98112
(206) 323-7175
By: William R. Bishin No. 8386

**CERTIFICATE OF SERVICE**

The undersigned served this Supplemental Brief on Respondent and Amicus on this date by placing it properly stamped in the U.S. MAIL addressed as follows:

Kim O'Neal, Esq.
P.O. Box 40100
Olympia, WA 98504

Kenneth S. Kagan, Esq.
Carney Badley Spellman
701 Fifth Avenue, Suite 3600
Seattle, WA 98104

Michael K. McCormack, Esq.
26828 Maple Valley Highway #242
Maple Valley, WA 98038-8309

June 24, 2009

/s/ *William R. Bishin*
WILLIAM R. BISHIN

## MOVING PARTY AND RELIEF REQUESTED

Petitioner Geoffrey S. Ames pursuant to RAP 12.4 asks the Court to reconsider and vacate or correct its decision and opinion entered on June 4, 2009 on the grounds and for the reasons set forth below.

## POINTS OF LAW, FACT, EVIDENCE AND PROCEDURE THAT THE COURT HAS OVERLOOKED OR MISAPPREHENDED

### Preliminary Statement

This is the case involving an alternative medical device used by the Petitioner in his allergy medicine practice. Petitioner argued that the Medical Commission Order finding him negligent and otherwise unprofessional for using a device it found to be inefficacious, was not supported by evidence, specifically necessary expert testimony, and that the doctrine that appeared to allow such findings based

only on the Commission's expertise should be disapproved. The Court has now held that the Order was based on expert testimony of the device's creator and an expert on biofeedback, to the effect that the device was not designed or approved for the use Petitioner made of it and that biofeedback machines cannot do what Petitioner does with it.

In doing so, the Court has decided this appeal on grounds – both factual and legal – that were not the grounds cited by the Medical Commission panel that entered the Findings, Conclusions and Order in this case, nor by any party in this case. Even though the Court holds the panel to be an expert body on the medical issues raised, it has interposed its own lay conceptions about, and lay interpretations of, relevant medical and technological evidence, standards, medical and regulatory practices and other facts.

It is not surprising that by taking on the expert function of the Commission in its evaluation of evidence, it misinterpreted the testimony of the two experts it relies on, James Clark and Richard Sherman. It misreads and gives that testimony a different interpretation than the one given by the Commission panel and a weight that the panel and its Order clearly did not give it. In usurping the Commission's expert function the Court has also applied uninformed lay assumptions and conceptions patently inconsistent with the facts of the medical profession, the standards of medical practice and medical science, and the regulation of medical devices. By so doing, the Court has reached a decision

that cannot withstand even minimal critical scrutiny: its holding is literally arbitrary, capricious, and even irrational. The result is to apply to the Petitioner standards that he could not anticipate beforehand and that cannot and will not be applied to other physicians and health care practitioners. By deciding the appeal on grounds that were not advanced in this case until it reached this Court, it has also blind sided Petitioner, depriving him of the right to respond to the case against him. The opinion is itself, therefore, a violation of due process and of equal protection under the State and Federal constitutions.

In addition, the insufficiency of the evidence on which the Court relies and the fact that the Court does not defend the actual rationale of the Commission's Order, but adopts its own rationale for it, suggests that the Court has simply decided – based on its own, non-record, lay experience – that the device in question cannot be used in the way the Petitioner used it. Apparently, because the Court has never heard of a device that could generate homeopathic signals, and because the idea seems so strange and bizarre, based on the Court's experience, it feels justified in relieving the Commission of its obligation to prove that the device was inefficacious for the purpose for which Dr. Ames used it. Either that or it has adopted an inarticulate policy of simply deferring to the Commission, at least with respect to alternative providers, because of the Commission's putative expertise, even as to alternative medical technology. A decision based on such grounds is a

decision based on undiluted lay prejudice. It reflects a lack of familiarity with the history of innovations in medicine and science, all to the prejudice of public policy and scientific progress, as well as to due process, equal protection, and the free inquiry values underlying state and federal protections of freedom of expression.

The Court's opinion also bestows a power on the FDA which was not intended by Congress and which interferes with the FDA's regulatory authority. The opinion gives FDA decisions not to approve a medical device for a particular purpose an authority and scope they were never intended to have and which the FDA may well not want. The opinion, therefore, violates the supremacy clause.

The argument supporting the specific points overlooked or misapprehended by the Court is set forth in the Argument section. For the Court's convenience, Petitioner lists those oversights and misapprehensions together as follows.

1. The opinion makes the mere "off-label" use of a medical device sufficient to establish that a physician has engaged in unprofessional conduct: this was not the ground of the Commission's decision and creates the extraordinary and absurd result of making virtually every physician who sees patients guilty of negligence

2. Neither in Logic Nor In Experience Is It Rational to Hold That A Device Designed For One Purpose, Cannot *Ipso Facto* Be Efficacious For Any Other Purpose

3. The Basis of the Commission's Decision and Findings: The Decision Was Not Based In Any Respect on the Clark or Sherman Testimony

4. The Court's Lay View of the Testimony of Mr. Clark and Dr. Sherman, Which the Commission Did Not Rely On, Led the Court to Misapprehend the Meaning and Significance of That Testimony

## ARGUMENT

### I. THE OPINION MAKES THE MERE "OFF-LABEL" USE OF A MEDICAL DEVICE SUFFICIENT TO ESTABLISH THAT A PHYSICIAN HAS ENGAGED IN UNPROFESSIONAL CONDUCT: THIS WAS NOT THE GROUND OF THE COMMISSION'S DECISION AND CREATES THE EXTRAORDINARY AND ABSURD RESULT OF MAKING VIRTUALLY EVERY PHYSICIAN WHO SEES PATIENTS GUILTY OF NEGLIGENCE

At page 9 of its opinion, the Court states as follows:

> Substantial evidence leads to the conclusion that Ames was using the LISTEN for purposes for which the machine was not designed or approved. As such no additional expert testimony was necessary to demonstrate the elements of professional misconduct.

The main testimony on which the Court relies in its opinion, it paraphrases as follows on page 8:

> Clark testified that the device was not submitted to the FDA for any diagnosis, treatment, or curing of allergies or any other ailments.

This holding and use of testimony – Dr. Sherman's testimony will be dealt with elsewhere – misunderstands FDA law and practice, specifically, the meaning of not having an FDA approval for a particular purpose. Lack of such approval establishes neither inefficacy nor negligence. There is other testimony of Mr. Clark that the Court could also rely on, but which it does not cite. That testimony will be discussed in Points III and IV, which address the Court's misapprehensions about the evidence the Commission panel actually relied on, and about the meaning of the evidence the Court invokes to uphold the Commission decision.

Our focus here is on the holding that using a machine for a purpose for which it "was not designed or approved" – *i.e.*, an off-label use – by itself establishes unprofessional conduct – *i.e.*, physician negligence and inefficacy of the device. This holding flies in the face of a basic fact of, everyday medical practice brought to the attention of the Court in Petitioner's briefing, but overlooked in the decision process.

In *Buckman v. Plaintiffs Legal Committee,* 531 U.S. 341, 350, 121 S.Ct. 1012, 1018 (2001), the United

States Supreme Court states that "off-label usage of medical devices" is "the use of a device for some ***other purposes*** than that for which it has been approved by the FDA." (Emphasis added.) Such use, the Court notes is "accepted and necessary" and "courts, several States, and the 'FDA itself recognize the value and propriety of off-label use.'" *Ibid.* In fact, as the Court noted, 21 U.S.C. § 396 protects the right of a health care practitioner" to use a device legally marketed for other purposes "for any condition or disease." *Ibid.*

The decision in the *Buckman* case turned on the Court's concern that using a state cause of action to piggyback onto the FDA's regulation of the marketing of medical devices would "deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, . . . and even though ***off-label use is generally accepted.***" (Emphasis added.) This court's opinion also deters off-label use by making the use of a legally marketed device *ipso facto* illegal because it was not "designed or approved" for the off-label use Petitioner made of it. Thus, this Court's opinion as written undermines the FDA's regulatory balance by adding to the consequences of its refusal to approve a device for every possible use it might have and "deter[ring] off label use," contrary to the intent of the FDCA. *Ibid.* at 350, at 1018.

If that is not bad enough, however, the Court's holding creates a rule that makes virtually every practicing physician guilty of unprofessional conduct. As the *Buckman* Court noted in quoting an article on

off-label use, "'Off-label use is ***widespread*** in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA and most courts recognize." *Id.* at 351, at 1019 (Emphasis added.) See Mayo Clinic, *Off-label Drugs and Medical Devices,* mayoclinic.com/health (October 1, 2007) ("Off-label use of drugs or medical devices isn't unusual. By some estimates, ***more than one out of every five drugs*** prescribed in the United States is for off-label use.") (Emphasis added.)

The Court's opinion is apparently based on the lay misconception that because a device has not been approved by the FDA it has been found to be inefficacious. As the Department's own FDA witness testified, this is not true. CR 2412-2414. There are many reasons, usually financial, why a device is not submitted for approval of a particular purpose and even when it is, the unwillingness of the FDA to approve does not mean that it is inefficacious, only that the FDA did not find the evidence submitted sufficient. *Ibid.* It is not a finding that the device cannot do what is claimed, as the *Buckman* decision necessarily implies.

Thus, even if this Court does not reconsider its decision, it should at a minimum rewrite it so that the rationale does not affect off-label use of devices or drugs.

***The Court's Rationale and Medical Theory Is Not in the Order Under Review.*** Finally, the theory that use of a device for a purpose for which it was not

designed or approved is itself negligence and in itself establishes a device to be inefficacious is not to be found in the Commission's Order. This is not surprising since such a theory is indefensible on its face and the Commission had been apprised of the law relating to off label uses.

## II. THE COURT OVERLOOKS THE FACT THAT NEITHER IN LOGIC NOR IN EXPERIENCE IS IT RATIONAL TO HOLD THAT BECAUSE A DEVICE IS DESIGNED FOR ONE PURPOSE, IT CANNOT *IPSO FACTO* BE EFFICACIOUS FOR ANY OTHER PURPOSE

Whether a device designed for one purpose can be used for another is a question of fact, not of logic. A book is designed to convey ideas by means of a bound text, but it can be used, among other things, as an object in a still life painting, as a weight to hold down papers, as a door stop, as a blunt object to kill a fly, as something to hold on one's head to practice good posture, as fuel for a fire. By merely establishing that the book was designed

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**NO. 248976**

COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON

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**GEOFFREY S. AMES, M.D.,**

Petitioner,

vs.

**WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,**

Respondent.

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ON APPEAL FROM THE SUPERIOR
COURT OF BENTON COUNTY,
THE HON. CARRIE RUNGE PRESIDING

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# OPENING BRIEF OF PETITIONER (CORR.)

---

William R. Bishin, P.S.
By: William R. Bishin WSBA No. 8386
1404 East Lynn, Seattle, WA 98112
(206) 323-7175
Attorneys for Geoffrey S. Ames, M.D.

## CERTIFICATE OF SERVICE

The foregoing Opening Brief of Petitioner was filed by mail with the Court on this date and served on respondent herein by depositing a copy in the United States mail first class postage pre-paid on this date and addressed as follows:

Kim O'Neal, Esq.
Assistant Attorney General
Office of Attorney General
1125 Washington S.E.
Olympia, WA 98504

July 31, 2006

/s/ *William R. Bishin*
WILLIAM R. BISHIN

## PRELIMINARY STATEMENT

This appeal is about a device sometimes used by an alternative physician as part of his procedure for assessing patients with possible allergies. Although a medical commission panel did not find that the physician had deceived or injured anyone, that he had acted in bad faith, or that the device was unsafe, it did rule that using it with a patient was "unprofessional conduct" under RCW 18.130.180(4) and (16). The device, based on Asian and homeopathic medical theories, was, the panel asserted, "inefficacious." Using it was, assertedly, negligence, and charging for the treatment to which it was related constituted "promotion for personal gain" of an "inefficacious" device. The panel suspended the physician's license, stayed the suspension on condition that he refrain from using the device, pay the Commission a $5,000 fine, and submit to regular practice reviews and reports to the Commission.

Petitioner contends that the Commission, believing but unable to prove, that the device could not work, lawlessly disregarded evidentiary norms,

procedural safeguards and the language of the relevant statutory scheme in order to suppress its use. The evidence and the findings were not only insufficient, they were grossly insufficient and it is difficult not to conclude that the panel's decision was a cynical manipulation of evidence, reasoning and statutory language to reach a result that could not be defended even by conventional medicine's professional and scientific standards, let alone by those the law insists upon. The decision poses a severe threat to alternative medicine generally, because if the "method" of prosecuting and deciding this case were upheld it could be used by any panel of conventional practitioners to suppress any alternative approach that has not been expressly identified and protected by the legislature. It would effectively allow the Commission to make its own law in cases involving alternative physicians and disregard the legislative policy favoring choice and patient freedom in those areas where conventional medicine has failed to meet patient needs. Thus, it is imperative that this Court not only overturn the decision, but that it do so in language that notifies the Commission that it will not tolerate an agency's playing fast and loose with procedural due process, no matter how truly the agency believes that the ends justify the means.

## ASSIGNMENTS OF ERROR

The Commission panel erred in entering the following findings of fact, because a reasonable fact-finder could not have found that they were supported

by *clear and convincing* evidence (or even by a preponderance) and, as to many of them, they had not been pleaded as required by Department of Health ("DOH") regulations, the Administrative Procedure Act (34.05 RCW) and due process:

1. ¶ 1.7, first sentence.

* * * *

they are not only insufficient, but grossly so and so disingenuous as also to be arbitrary and capricious. *See e.g.*, ***Olmstead v. Department of Health***, 61 Wn.App. 888, 895, 812 P.2d 527 (Div. 1,1991). Similarly, but more obviously, although under ***Johnston***, DOH need not, at least in cases like ***Johnston***, introduce specific evidence of the assertedly applicable conventional standard of care, it is not relieved of the burden of introducing clear and convincing evidence of every other element constituting alleged unprofessional conduct. For example, ***Johnston*** does not relieve DOH of the need to establish that Dr. Ames's conduct created an "unreasonable risk" of harm to a patient, and that the device in this case was "inefficacious" and "promot[ed] for "personal gain."

Thus, ***Johnston*** and ***Davidson*** stand only for the proposition that the panel members in making a negligence determination may use the general, background knowledge that they have acquired through their training and experience to evaluate and draw inferences from the evidence that was introduced. *E.g.*, ***Brown***, at 105 ("agency may use its experience

and specialized knowledge to evaluate and draw inferences from the evidence"). There must still be clear and convincing evidence of record from which the rational, fair-minded fact-finder can infer the necessary ultimate fact. Compare, *e.g.*, ***Franz v. Board of Medical Quality Assurance***, *supra* at 142-143 (record must disclose the basis of the panel's expert opinion).[16]

## II. THE EVIDENCE THAT DR. AMES WAS NEGLIGENT FOR USING THE LISTEN IS GROSSLY INSUFFICIENT, INDEED, DISINGENUOUS

### A. Why There is a Special Need For Clear and Convincing Evidence in this Case

The Commission charged Dr. Ames with unprofessional conduct for using the LISTEN in assessing P1. It thus had the burden of production and persuasion as to each fact on which it based this quasi-criminal charge. WAC 246-11-520 ("the burden is on the department to prove the alleged factual basis of the initiating document"); ***Nguyen v. Medical***

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[16] ***Johnston***'s holding about standard of care evidence – which was not the primary holding in that case – was cursory, incidental, almost casual, and the Court did not appear to be aware that its position was a minority one, raising serious due process and other problems. If Dr. Ames were forced to challenge it in the Supreme Court that it would not likely survive. See *Martin v. Sizemore*, 78 S.W.3d 249 (Tenn.Ct.App. 2001) for the reasons.

***Quality Assurance Commission***, 144 Wn.2d 516, 29 P.3d 689 (2001). Because it is a quasi-criminal charge involving severe professional consequences, because the public invests in and needs the services of highly-trained health care practitioners, and because error is likelier on charges adjudicated by part-time agency members combining judicial, legislative and executive functions, and acting "as investigator, prosecutor, and decisionmaker" (***Painter v. Abels***, 998 P.2d 931 (Wyo. 2000), see footnote 3, *supra*.), Washington requires that DOH's proof be "clear and convincing" ***Nguyen***, *supra*.

* * * *

NO. 80644-6

**SUPREME COURT OF THE STATE OF WASHINGTON**

GEOFFREY S. AMES, M.D.,

Petitioner,

v.

WASHINGTON STATE HEALTH DEPARTMENT AND MEDICAL QUALITY ASSURANCE COMMISSION,

Respondent.

# RESPONDENTS' ANSWER TO PETITION FOR DISCRETIONARY REVIEW

ROBERT M. MCKENNA
Attorney General

KIM O'NEAL, WSBA #12939
Senior Counsel
PO BOX 40100
Olympia, WA 98504-0100
(360) 664-9006

## I. IDENTITY OF RESPONDENTS

The Respondent is the Washington State Health Department ("Department") and Medical Quality Assurance Commission ("Commission").

## II. OPINION OF THE COURT OF APPEALS

Division Three of the Court of Appeals affirmed the Final Order of the Medical Quality Assurance Commission in this matter in its opinion No. 24897-III dated May 17, 2007, and denied Dr. Ames' motion for reconsideration on August 2, 2007. Those opinions are contained in the Appendix to Dr. Ames' Petition for Discretionary Review.

## III. COUNTERSTATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Under settled Washington law, are Commission members entitled to use their expertise to consider the evidence and draw inferences from facts presented in the record when deciding whether a physician has provided treatment below the standard of care?

2. Where the charging document notified Dr. Ames of the patient, the two specific dates of treatment, and the statutes allegedly violated, did the charges meet the statutory and constitutional due process requirements for notice?

* * * *

## RCW 18.130.180 §§ (1), (4), (7), (16)

### 18.130.180. Unprofessional conduct

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. . . .

. . . .

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

. . . .

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

. . . .

(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

. . . .

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**WASHINGTON ADMINISTRATIVE CODE**
**§§ WAC 246-11-250, 246-11-260, 246-11-520**

**SECTION II**
**INITIATING ACTIONS**

**WAC 246-11-250 Form and content of initiating documents.** (1) Initiating documents shall include a clear and concise statement of the:

(a) Identity and authority of the person issuing the document;

(b) Factual basis for the action or proposed action set forth in the document;

(c) Statutes and rules alleged to be at issue;

(d) Identity of the party against whom the action is taken or proposed to be taken;

(e) Action or proposed action or penalties, including the statutory or rule authority for those actions or penalties;

(f) Signature of the person issuing the document and the date signed; and

(g) Method by which an adjudicative proceeding may be requested.

(2) Initiating documents shall be accompanied by the following documents:

(a) Notice that the respondent may defend against the action or proposed action; and

(b) Form for requesting adjudicative proceeding.

(3) Initiating documents shall be served as described in WAC 246-11-080.

* * * *

**WAC 246-11-260 Amendment of initiating documents.** (1) Prior to the hearing date, initiating documents may be amended subject to the following conditions:

(a) Amended initiating documents shall meet the requirements of WAC 246-11-250(1);

(b) Amended initiating documents shall be accompanied by the documents described in WAC 246-11-250(2);

(c) Whenever amended initiating documents are issued, a new interval for response will begin, as described in WAC 246-11-270, unless the respondent requests the time periods set by the original initiating document; and

(d) Issuance of amended initiating documents ends all obligations of the parties under the prior initiating documents.

(2) On the hearing date, the initiating documents may be amended subject to the following conditions:

(a) The documents may be amended upon motion of the state;

(b) The documents may not be amended without the approval of the presiding officer; and

(c) Upon motion of a party or upon his/her own initiative, the presiding officer may grant a continuance on all or part of the matter if necessary to afford the respondent an opportunity to prepare a defense to the amended documents.

* * * *

**WAC 246-11-520 Standard of Proof.** The order shall be based on the kind of evidence upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs. In all cases involving an application for license the burden shall be on the applicant to establish that the application meets all applicable criteria. In all other cases the burden is on the department to prove the alleged factual basis set forth in the initiating document. Except as otherwise provided by statute, the burden in all cases is a preponderance of the evidence.

* * * *

## RCW 34.05.452(5)

### 34.05.452. Rules of evidence – Cross-examination

. . . .

(5) Official notice may be taken of (a) any judicially cognizable facts, (b) technical or scientific facts within the agency's specialized knowledge, and (c) codes or standards that have been adopted by an agency of the United States, of this state or of another state, or by a nationally recognized organization or association. Parties shall be notified either before or during hearing, or by reference in preliminary reports or otherwise, of the material so noticed and the sources thereof, including any staff memoranda and data, and they shall be afforded an opportunity to contest the facts and material so noticed. A party proposing that official notice be taken may be required to produce a copy of the material to be noticed.

* * * *

## RCW 34.05.461

(1) Except as provided in subsection (2) of this section:

. . . .

(3) Initial and final orders shall include a statement of findings and conclusions, and the reasons and basis therefor, on all the material issues of fact, law, or discretion presented on the record, including the remedy or sanction and, if applicable, the action

taken on a petition for a stay of effectiveness. Any findings based substantially on credibility of evidence or demeanor of witnesses shall be so identified. Findings set forth in language that is essentially a repetition or paraphrase of the relevant provision of law shall be accompanied by a concise and explicit statement of the underlying evidence of record to support the findings. The order shall also include a statement of the available procedures and time limits for seeking reconsideration or other administrative relief. An initial order shall include a statement of any circumstances under which the initial order, without further notice, may become a final order.

(4) Findings of fact shall be based exclusively on the evidence of record in the adjudicative proceeding and on matters officially noticed in that proceeding. Findings shall be based on the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. Findings may be based on such evidence even if it would be inadmissible in a civil trial. However, the presiding officer shall not base a finding exclusively on such inadmissible evidence unless the presiding officer determines that doing so would not unduly abridge the parties' opportunities to confront witnesses and rebut evidence. The basis for this determination shall appear in the order.

(5) Where it bears on the issues presented, the agency's experience, technical competency, and specialized knowledge may be used in the evaluation of evidence.

. . . .

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**21 U.S.C. § 360c(E)(i)**

Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the ""Director"") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing. . . .

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**SUPERIOR COURT FOR BENTON COUNTY**
**STATE OF WASHINGTON**

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| GEOFFREY S. AMES, M.D.,<br>Petitioner,<br>v.<br>WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,<br>Respondent. | **NO. 04-2-01837-1**<br>**PETITIONER'S OPENING BRIEF** |

**CERTIFICATE OF SERVICE**

The undersigned caused the foregoing Petitioner's Opening Brief to be served upon Respondent by arranging for its delivery on April 18, 2005 at the following addresses:

Kim O'Neal, Esq.
Assistant Attorney General
Office of Attorney General
1125 Washington S.E.
Olympia, WA 98504

April 18, 2005

/s/ *William R. Bishin*
WILLIAM R. BISHIN WSBA NO. 838B

* * * *

using acupuncture with unprofessional conduct for checking pulses – perhaps the most common

diagnostic technique used in that Asian specialty – in order to determine the patient's energetic balance. The Commission could then call no witnesses as to the harm or inadequacy of the practice, confining itself to putting on testimony that the licensee in fact did use pulse readings to diagnose his patients. The deficiencies in the evidence would be made up by the supposed expert knowledge possessed by the panel members.

*Johnston* and the other cases each contain statements that DOH need not introduce specific expert testimony of the standard of care when it prosecutes a licensee for negligence, since a panel of licensees is presumed to know the standard of care. *Johnston* and the other decisions, insofar as they dealt with this issue, were not based on full briefing, do not discuss contrary authority, do not discuss the due process and judicial review issues involved and appear to be unaware that their position is a minority one.[footnote omitted] For a discussion of this and of the many issues the *Johnston, Davidson* and *Brown* opinions do not address, see, *e.g., Martin v. Sizemore*, 78 S.W.3d 249, 271 (Tenn.Ct.App.2001); *Drew v. Psychiatric Sec. Rev. Bd, supra*; and *Painter v. Abels, supra*, a case relied upon

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opportunity to seek a continuance. No such motion was made at any time.

The requirement of notice and an opportunity to defend is elementary to every lawyer and judge.

*E.g., State v. Perry*, 96 Wn.App. 1, 5, 975 P.2d 6, 8 (Div. 1 1999). The APA requires that the notice of a hearing must include "a short and plain statement of the matters asserted by the agency" or if the agency is unable to state all of the facts, a "statement of the issues involved." RCW 34.05.434(2), (3). The agency was not unable. The record taken as a whole shows it was in possession of the relevant facts. But neither a plain statement of the facts relating to the matters discussed below nor a statement of the issues relating to them appeared even in the amended statement of charges. See generally, *e.g., Olmstead v. Dept. of Health*, 61 Wn.App. 888, 892, 812 P.2d 527, 530 (1991); *Cooper v. Board of Prof. Disc.*, 134 Idaho 449, 4 P.3d 561, 567 (Id. 2000); RCW 34.05.434(2), (3);

The amended statement of charges alleged in sum as follows: that on June 6, 2001, Dr. Ames had seen Patient One, who complained of chronic fatigue. ¶1.13. Dr. Ames "ordered urine and blood tests and hair analysis." *Ibid.* On July 10, 2001, Patient One had another visit in which the test results were discussed and Dr. Ames told him that the blood tests showed a number of food allergies. ¶1.14. Dr. Ames then tested Patient One's muscles by applying pressure to his extended arm and Patient One was able to hold his arm up. Ibid. Dr. Ames then allegedly had him hold a brass rod connected to the LISTEN in his hand while the doctor "typed in 'eggs' into the device. Ibid. When Patient One was then tested a

second time, he was unable to resist. Ibid. This, Dr. Ames allegedly said, showed

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